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Ostfeld et al.

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(54) **INDWELLING DEVICE**

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(73) Assignee: **Ishay Ostfeld**, Ramnat Gan (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 393 days.

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(65) **Prior Publication Data**

US 2010/0298754 A1 Nov. 25, 2010

Related U.S. Application Data

(63) Continuation of application No. 10/916,631, filed on Aug. 12, 2004, now abandoned, which is a continuation-in-part of application No. 10/074,017, filed on Feb. 14, 2002, now abandoned.

(51) **Int. Cl.**
A61M 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/171**

(58) **Field of Classification Search**
USPC 604/171, 192, 349, 544
See application file for complete search history.

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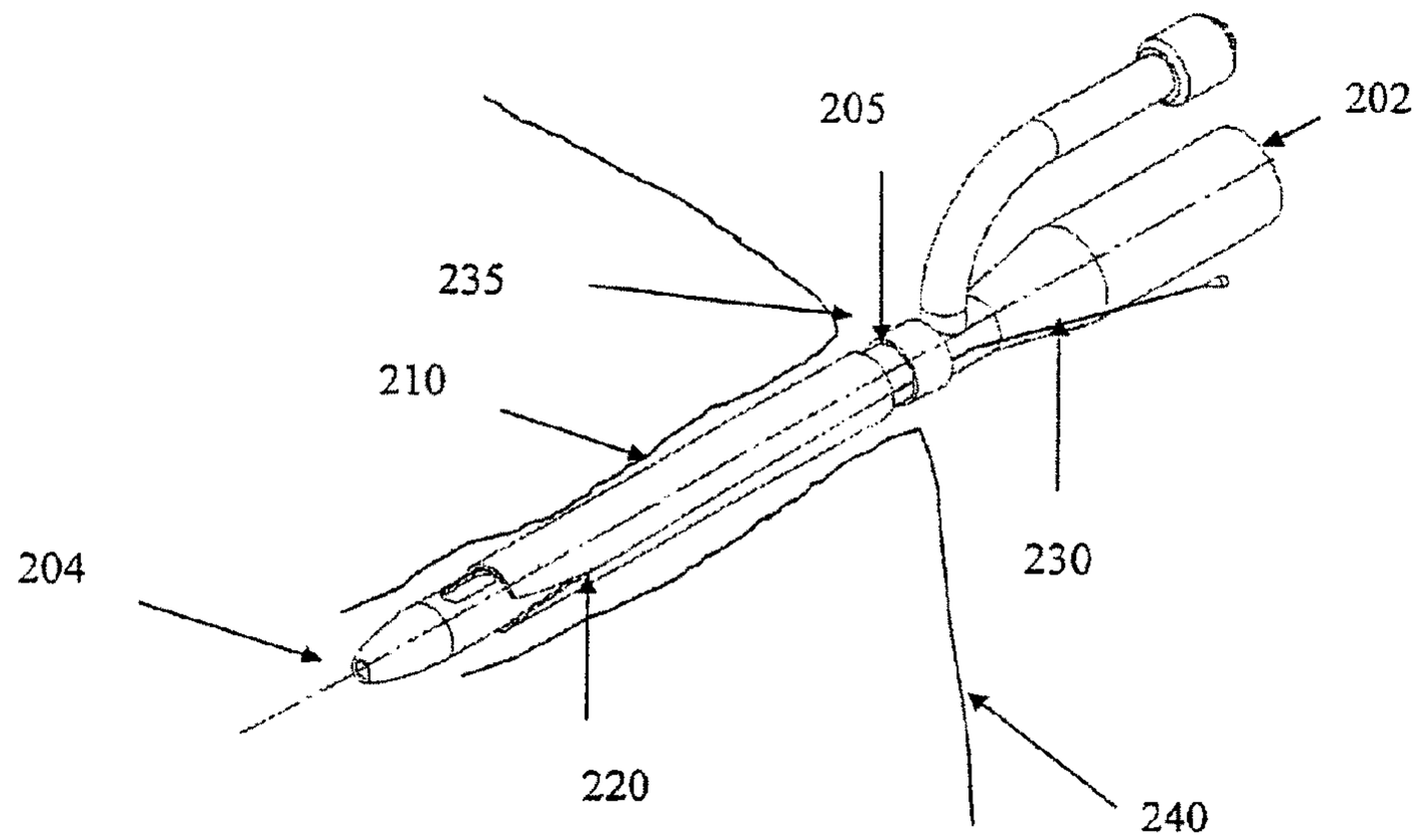
(57) **ABSTRACT**

A medical device for insertion into a body having a surface covered by a detachable cover. The cover may be detached from the surface and removed from the body while the device is inserted in the body. The device may be, for example, a catheter, cannula, drain, stent, pacemaker, or electrode.

41 Claims, 24 Drawing Sheets



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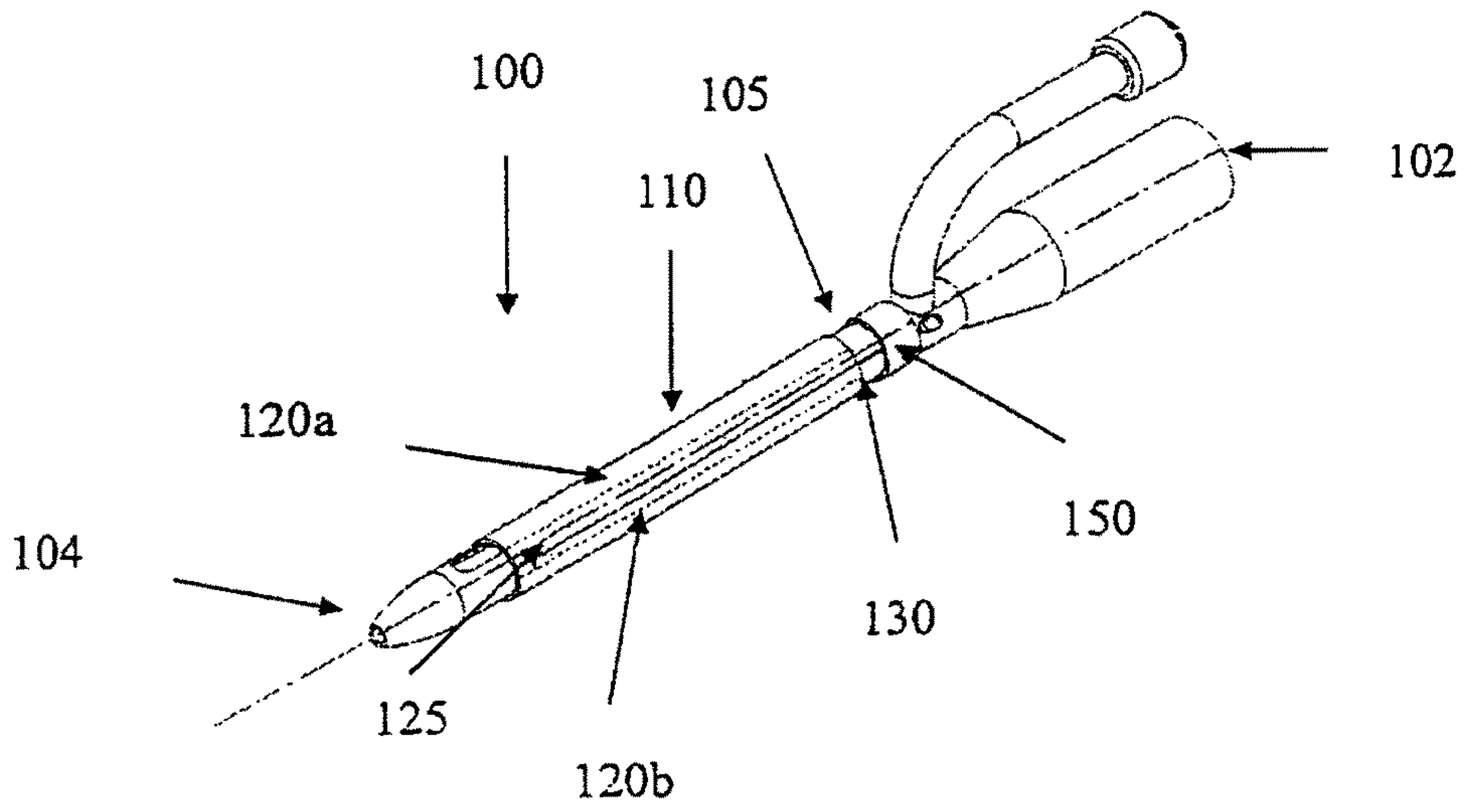
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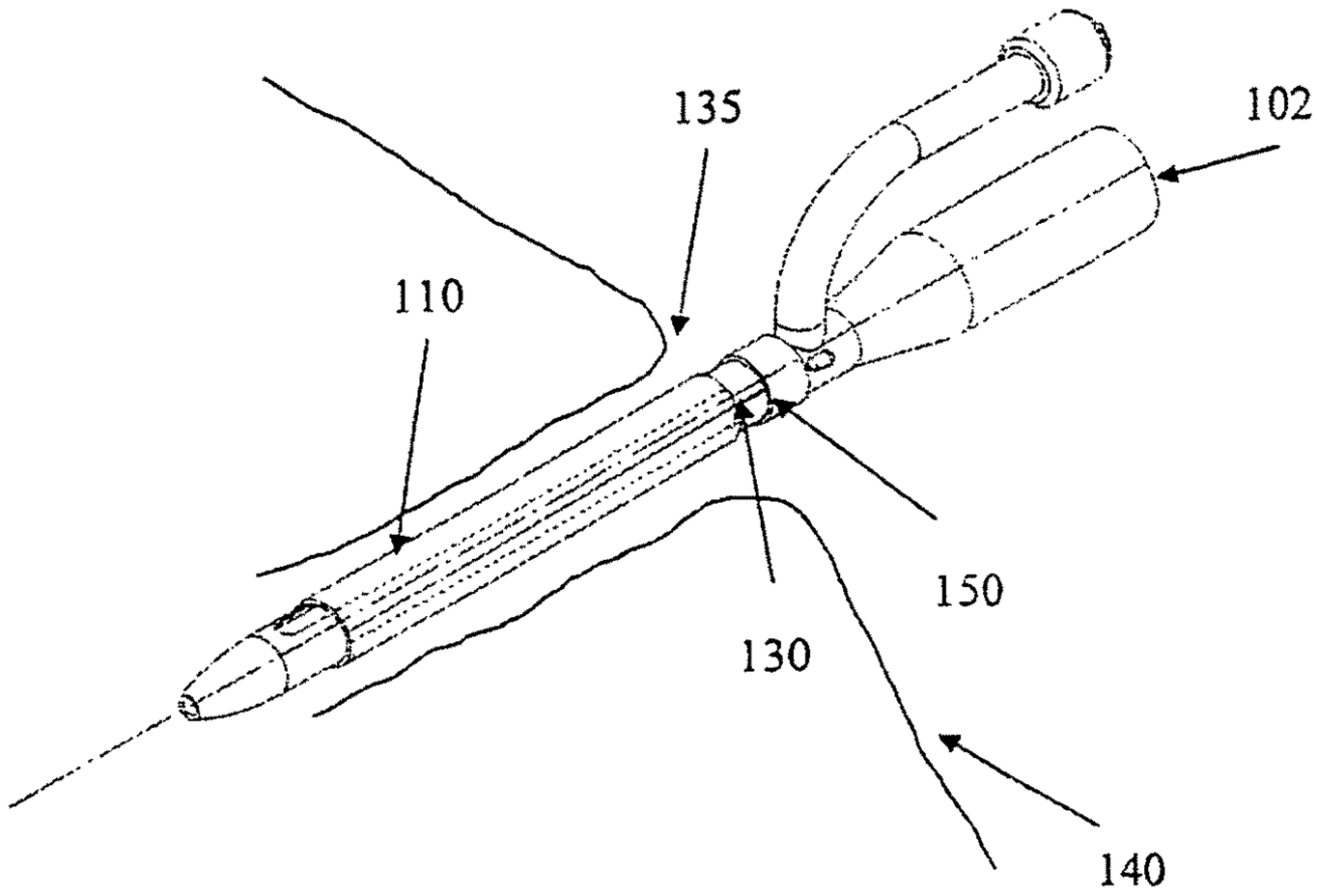
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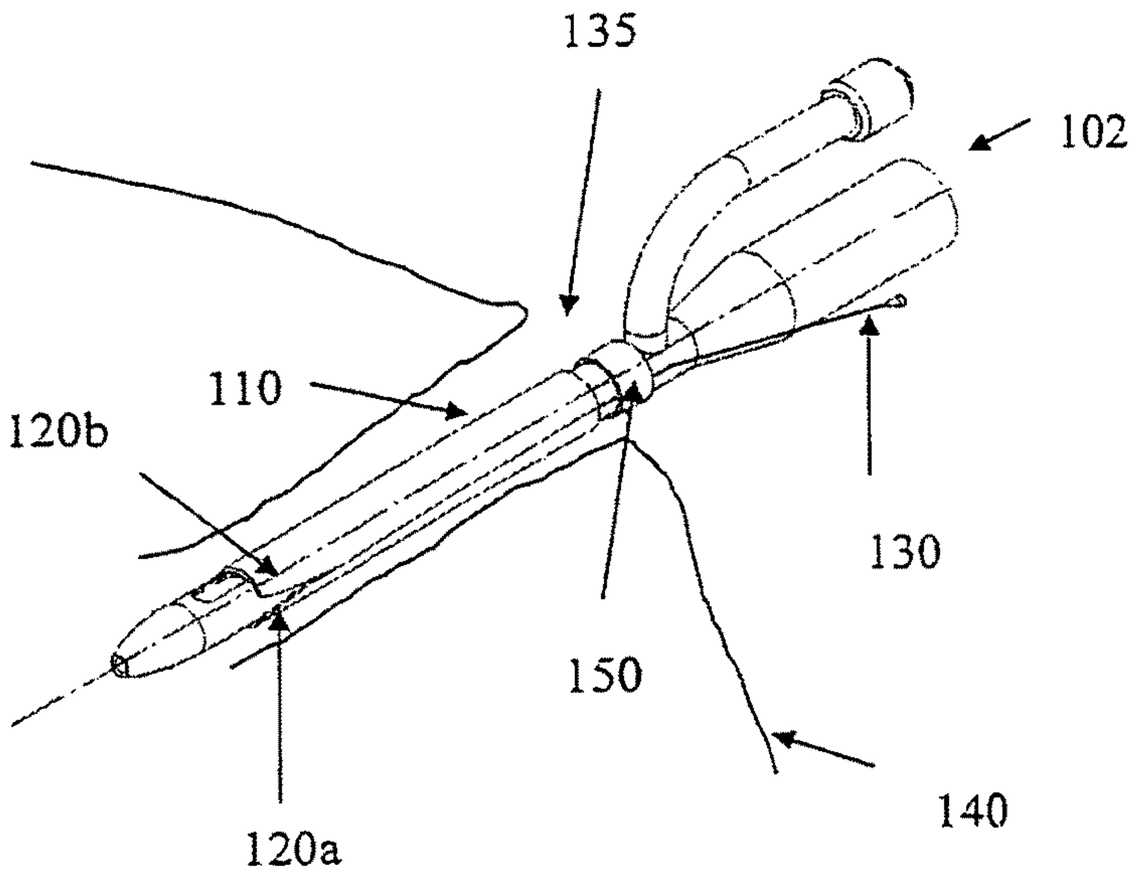
Fig.1b



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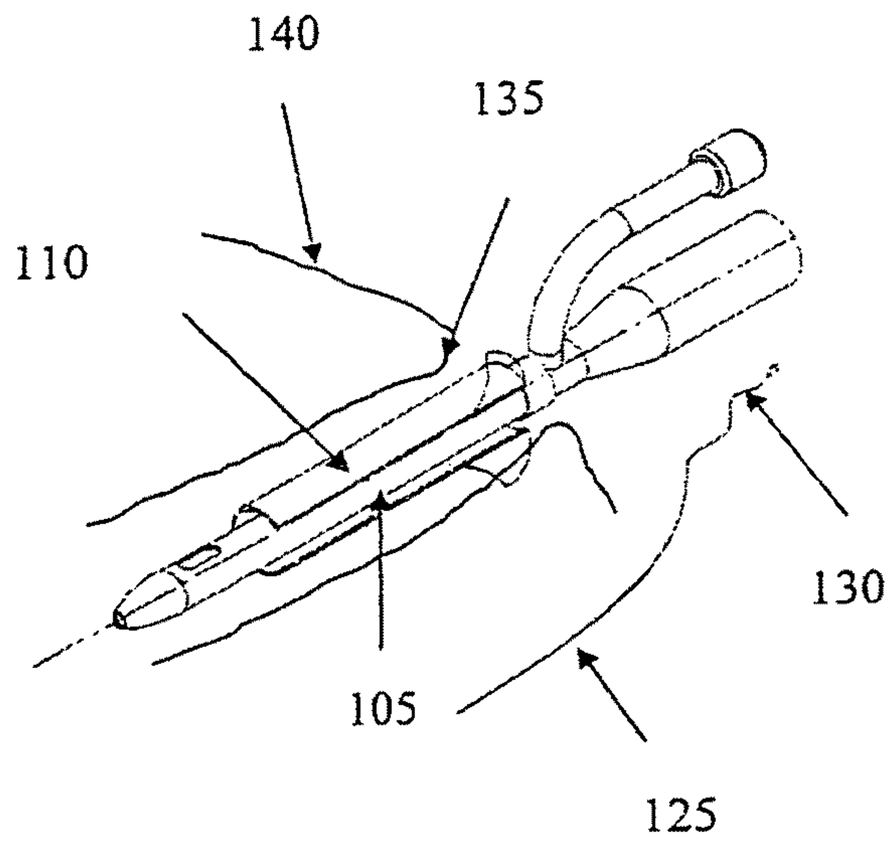


Fig.1d

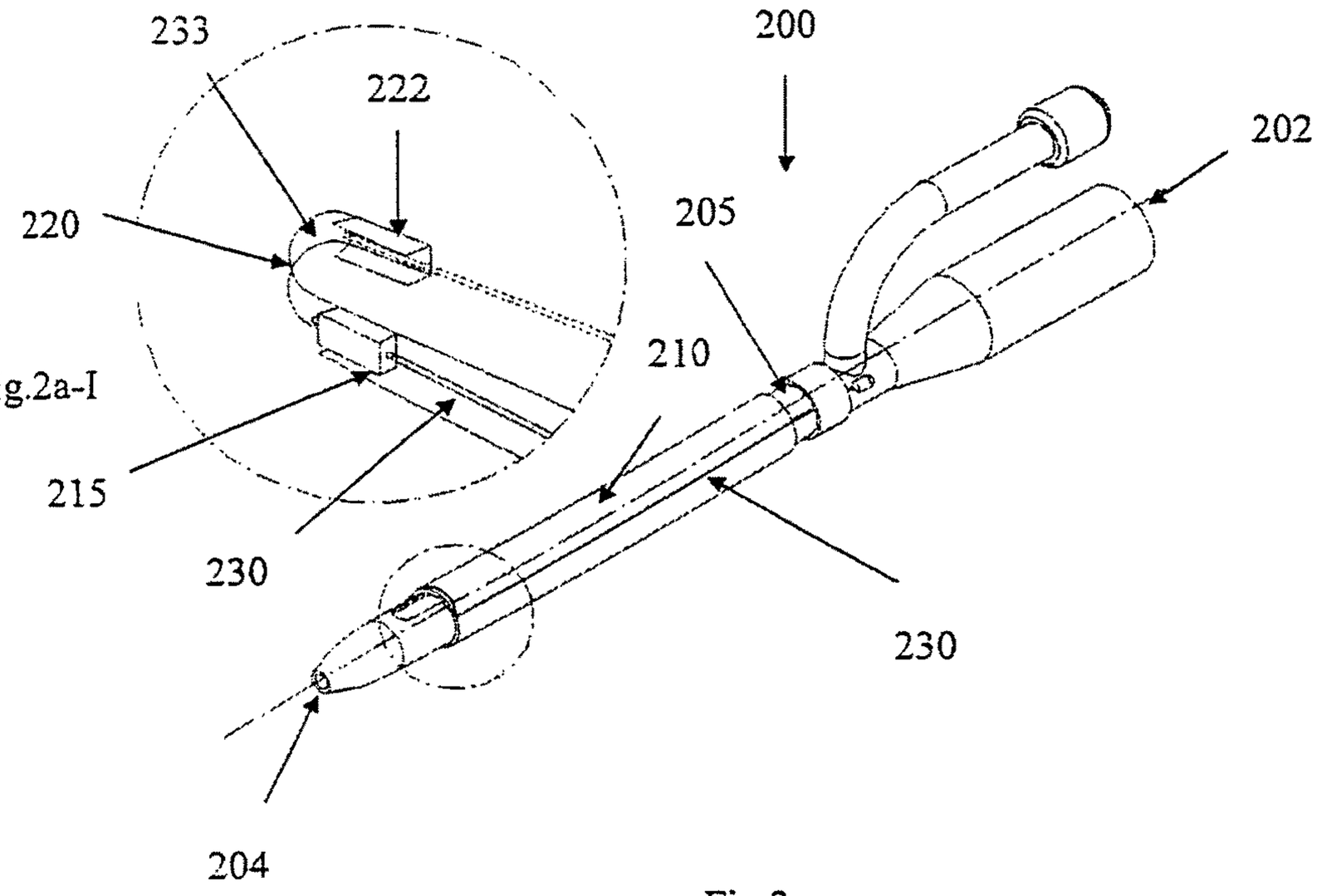


Fig.2a-I

Fig.2a

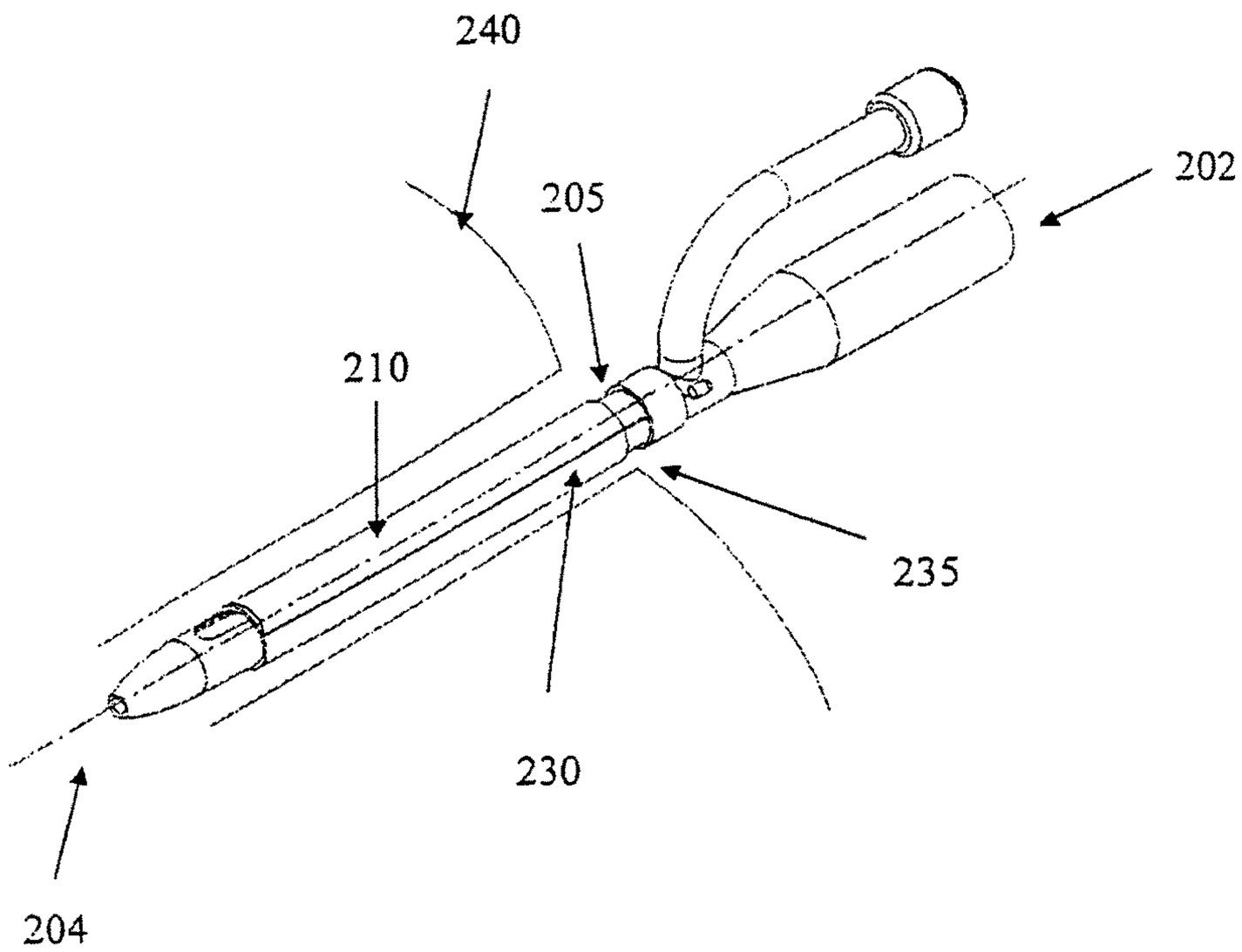
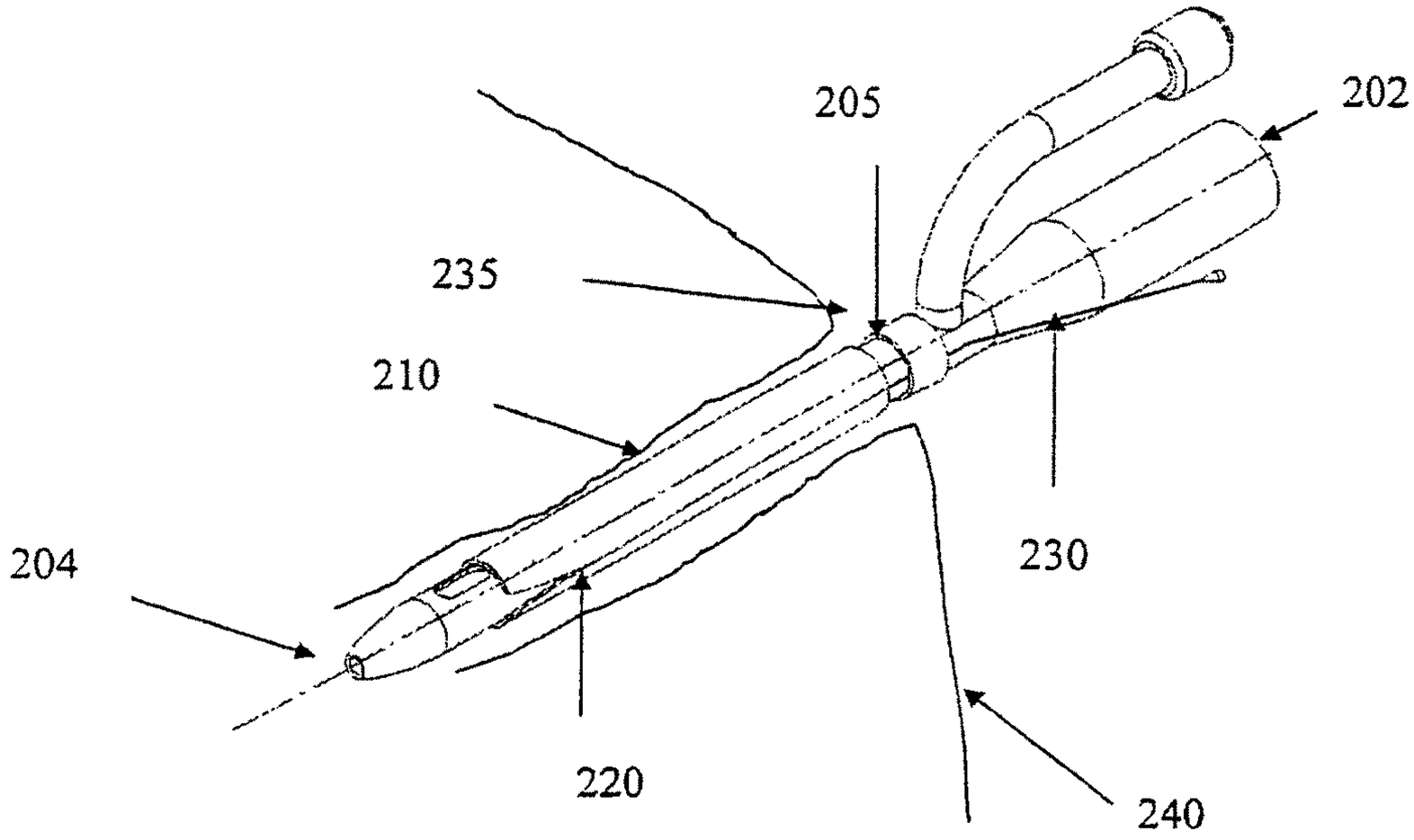


Fig 2b



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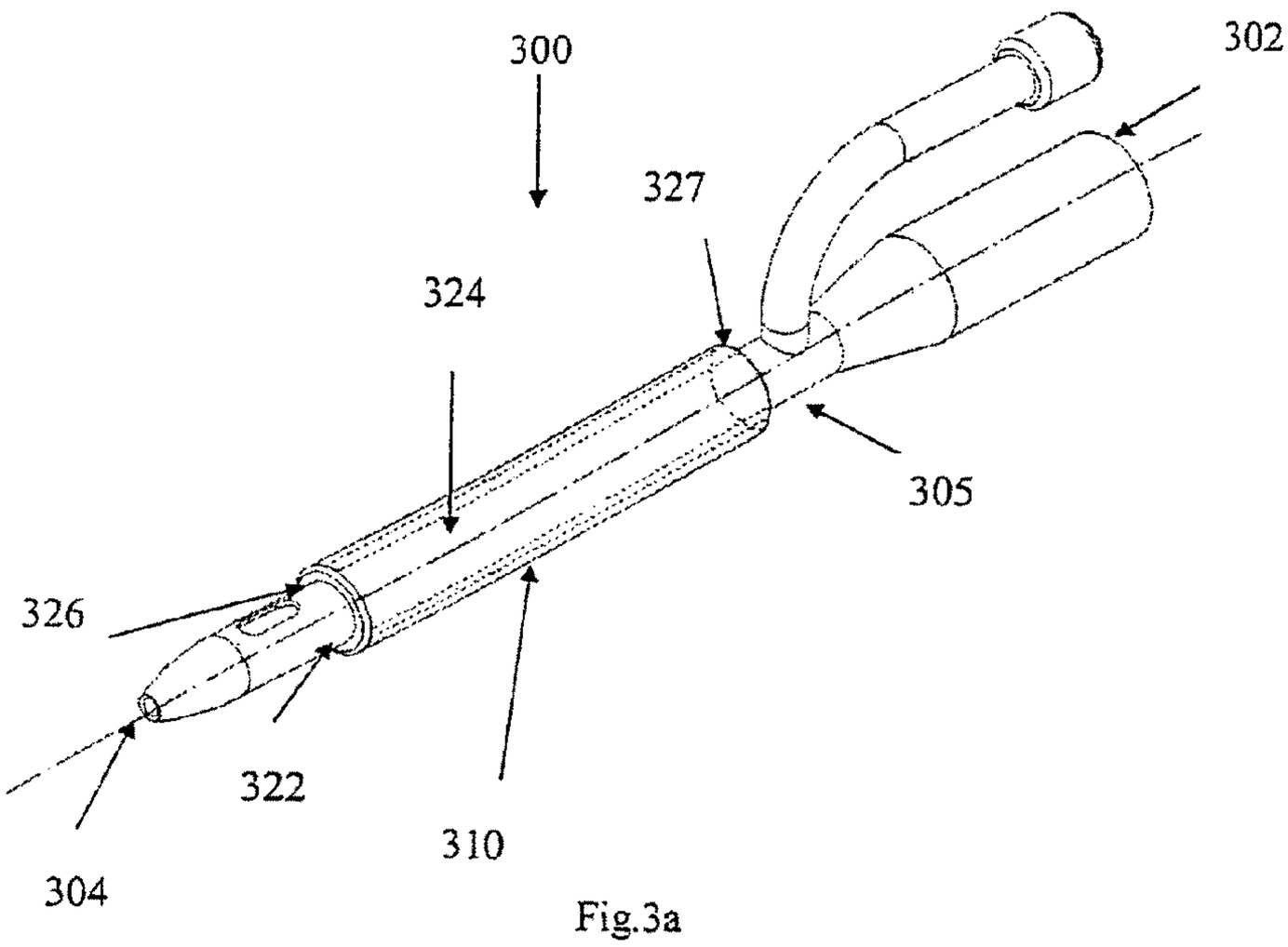

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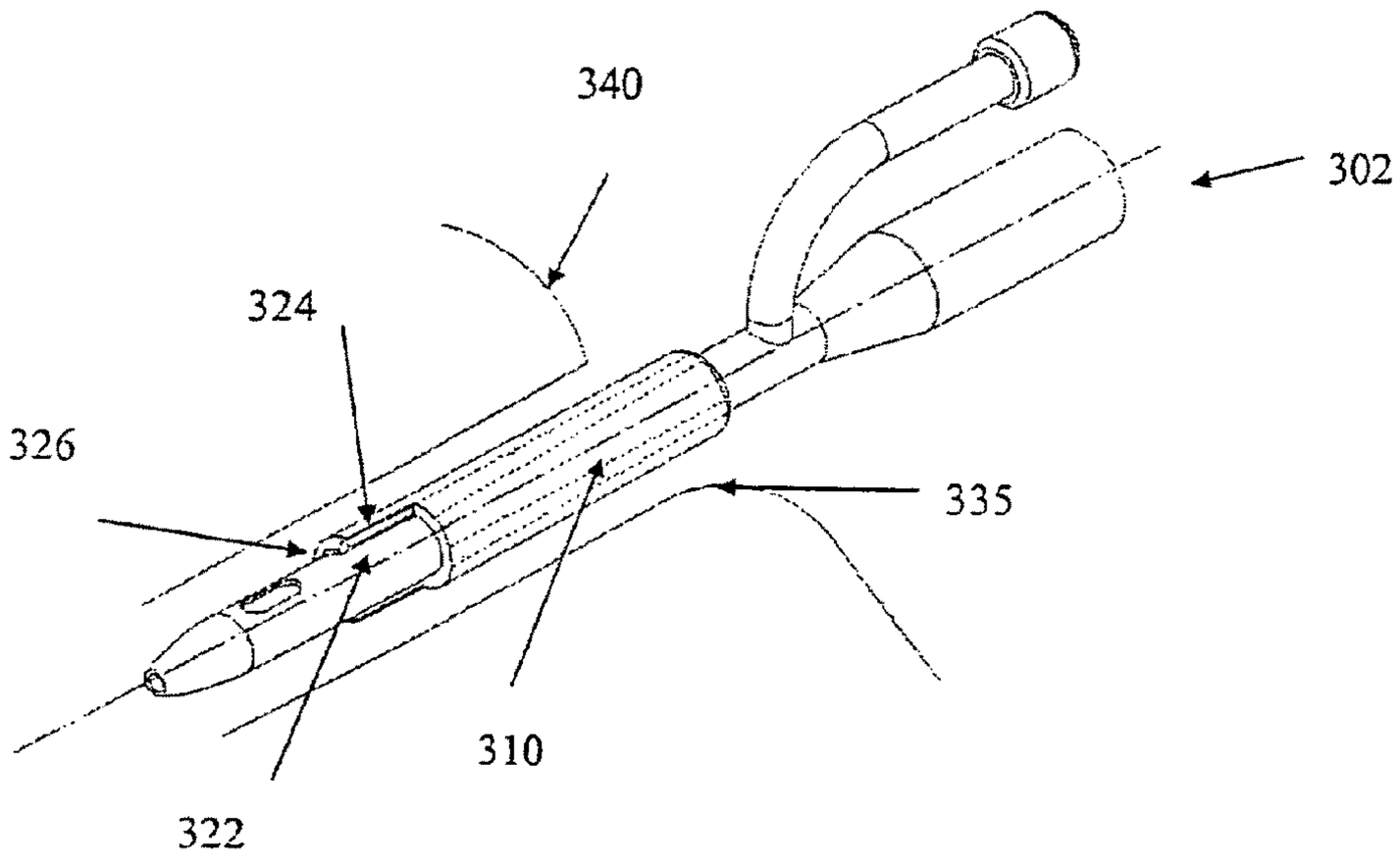

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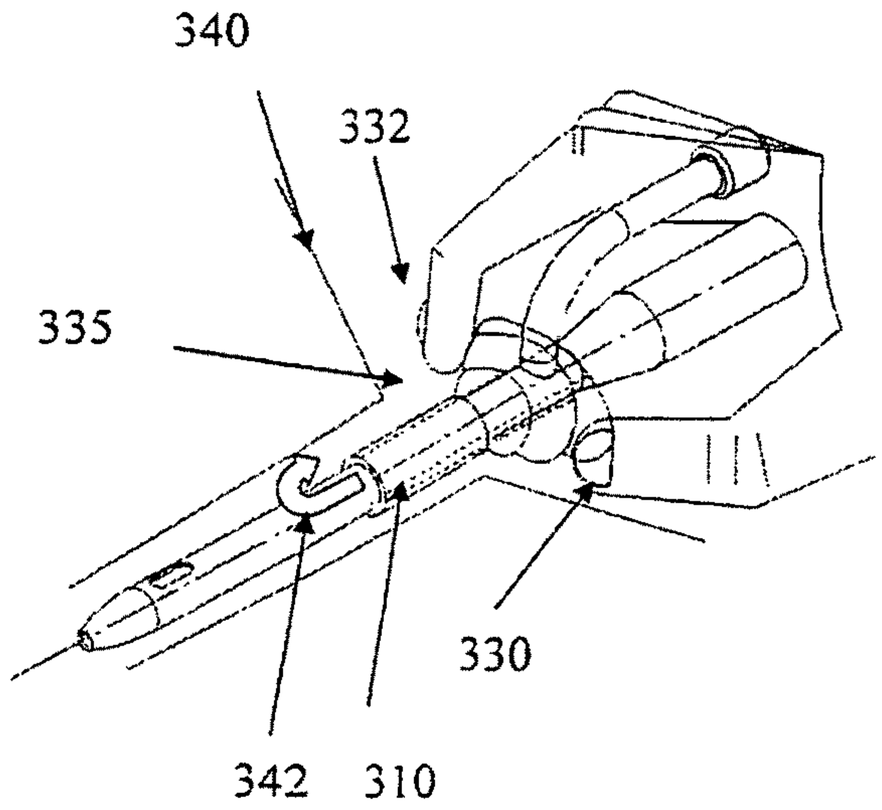

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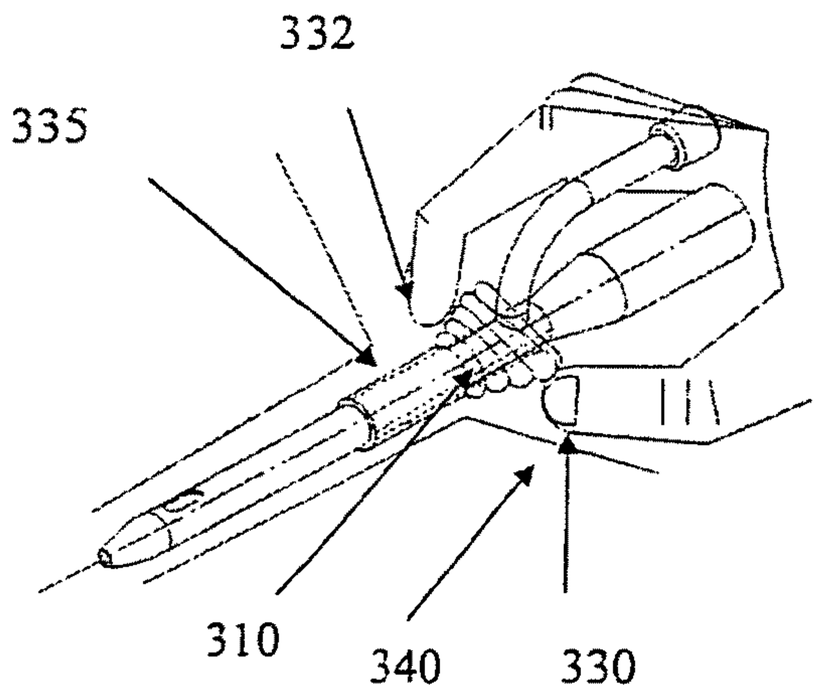

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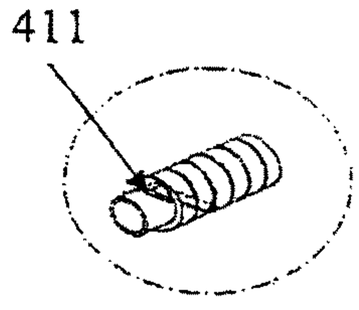


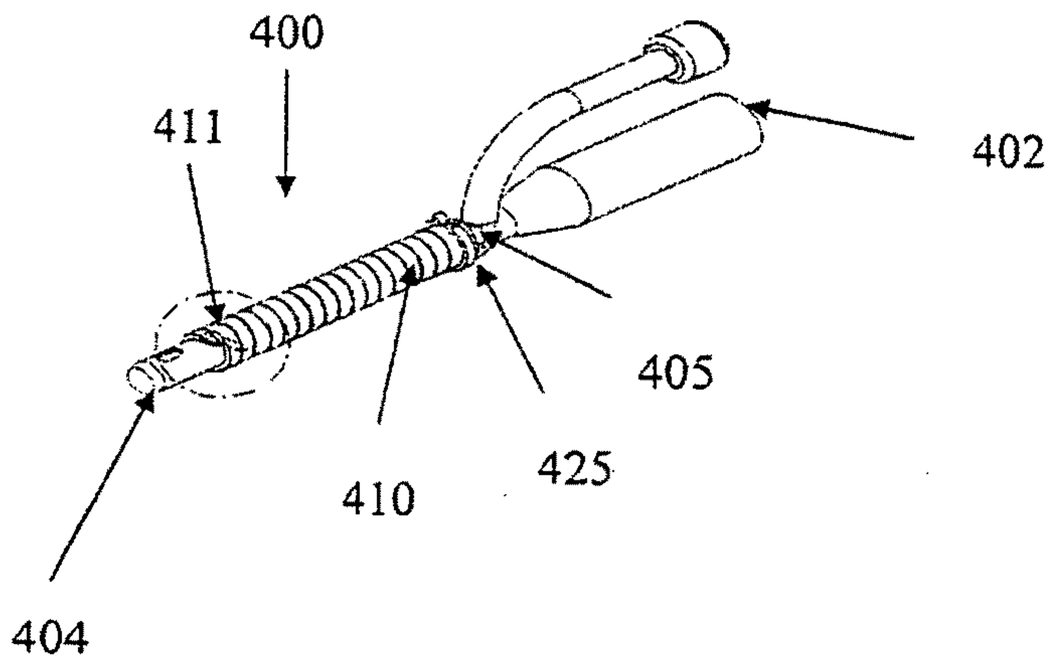
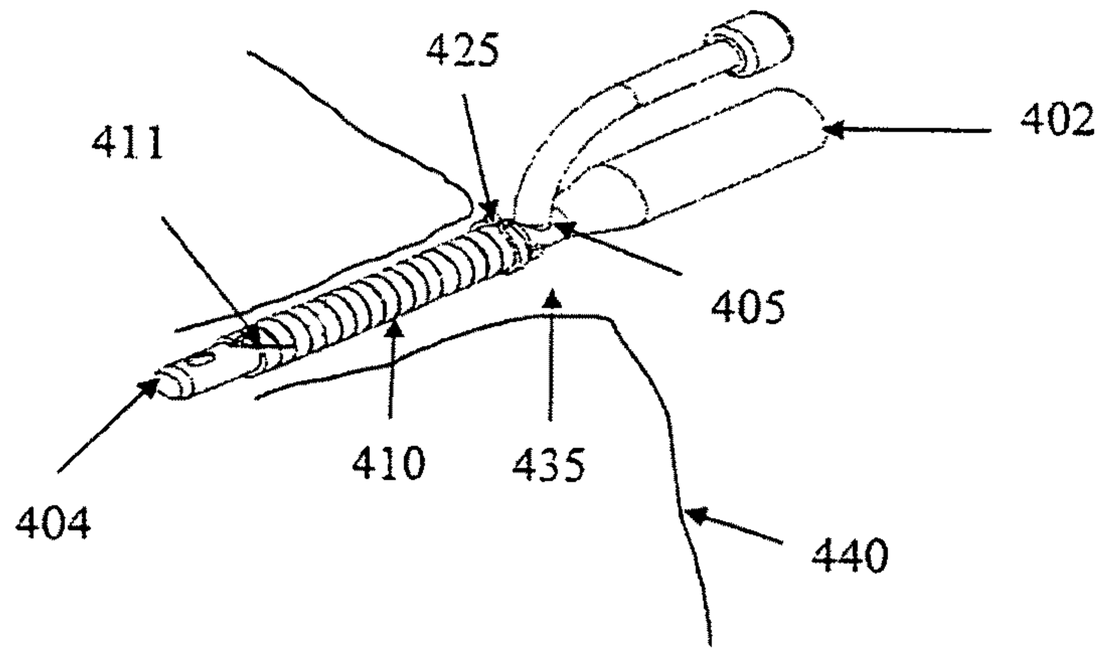


Fig. 4a



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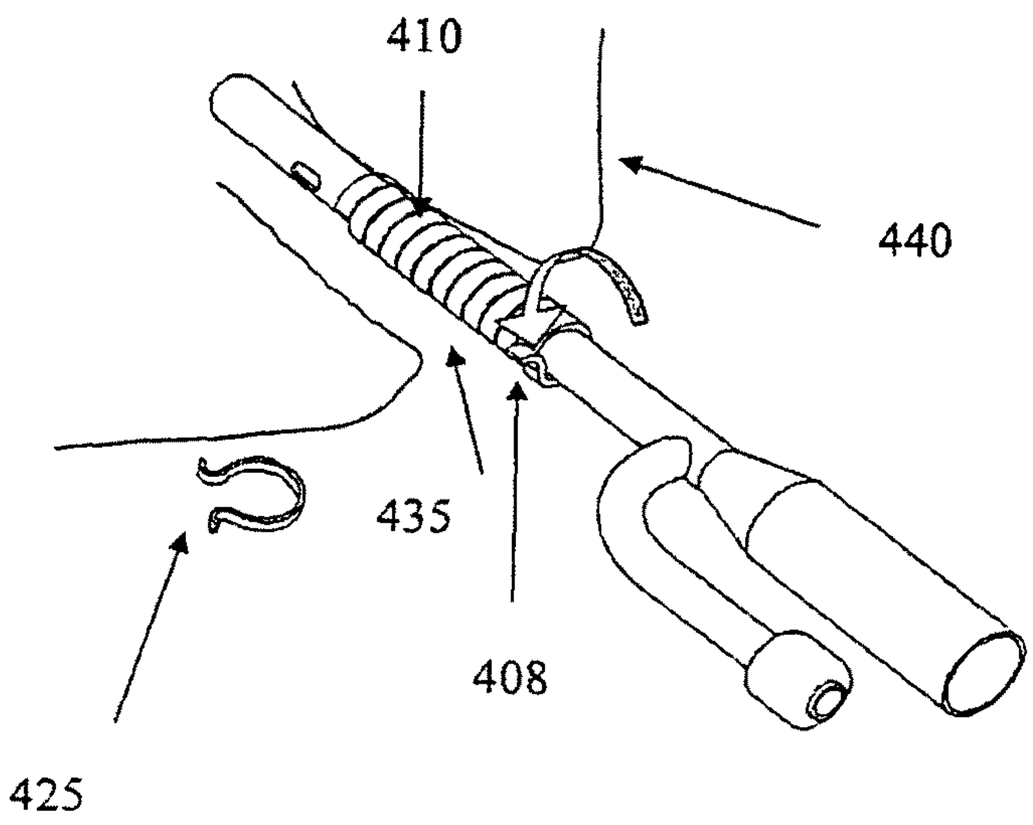

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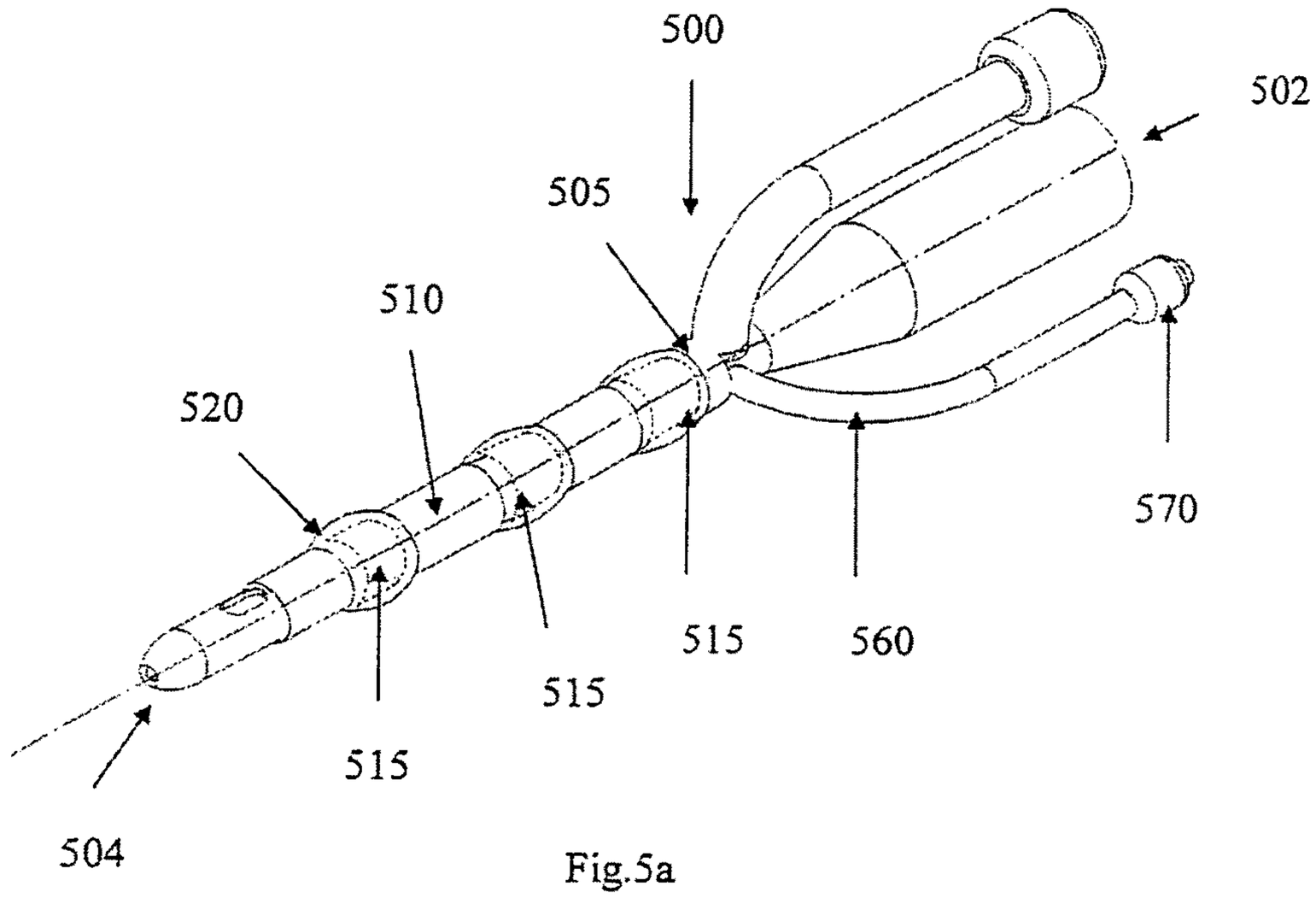
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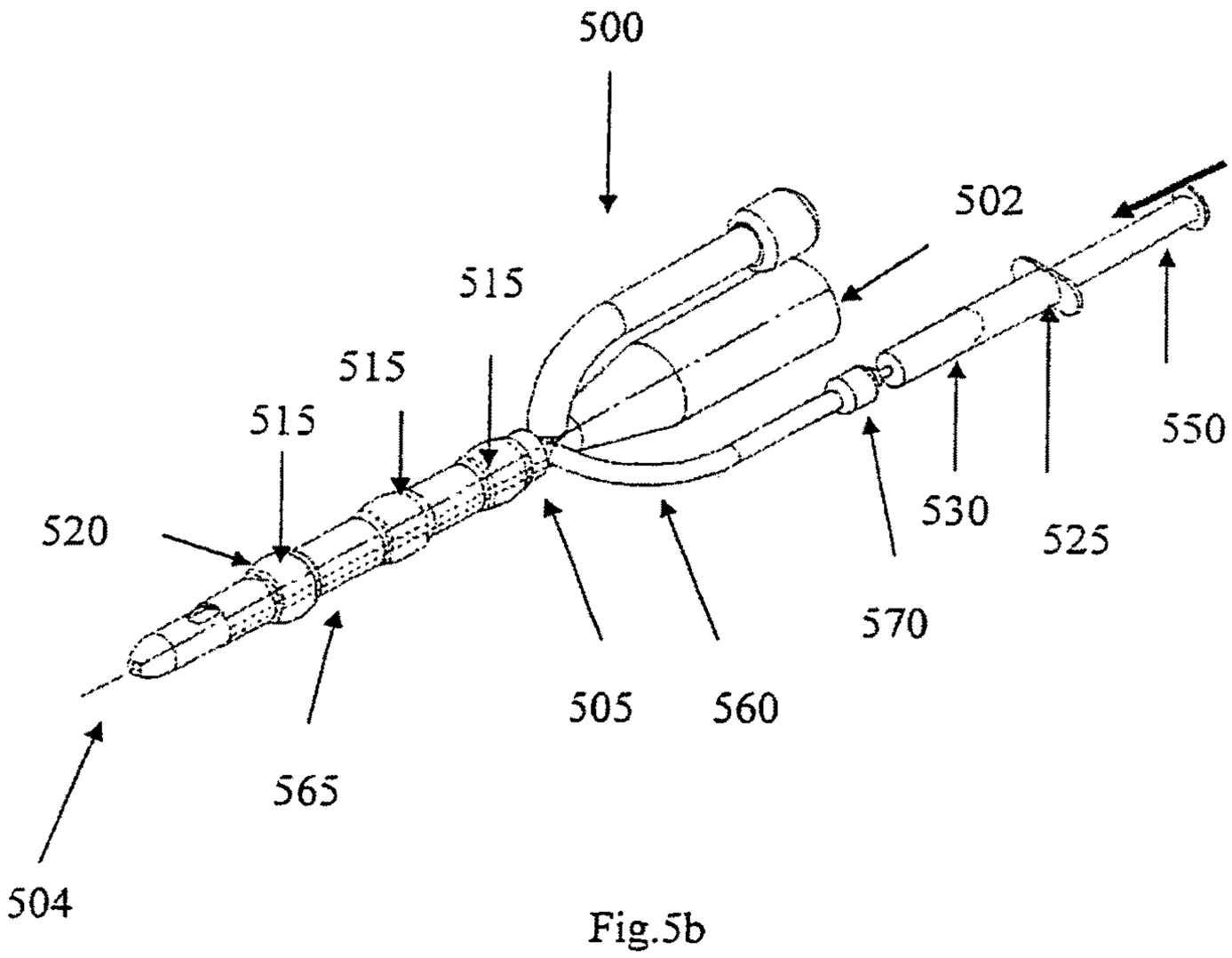
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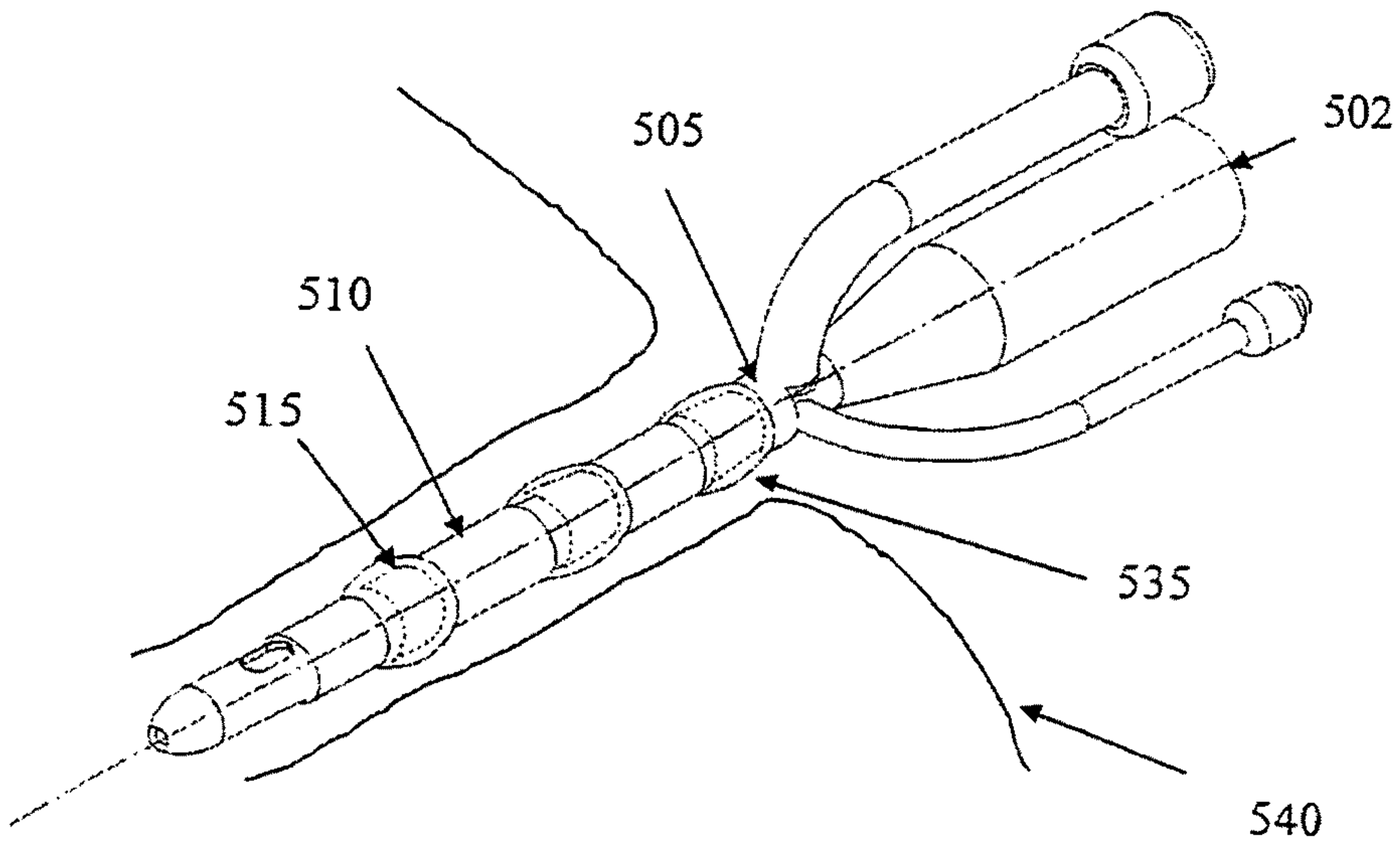
Fig.5b



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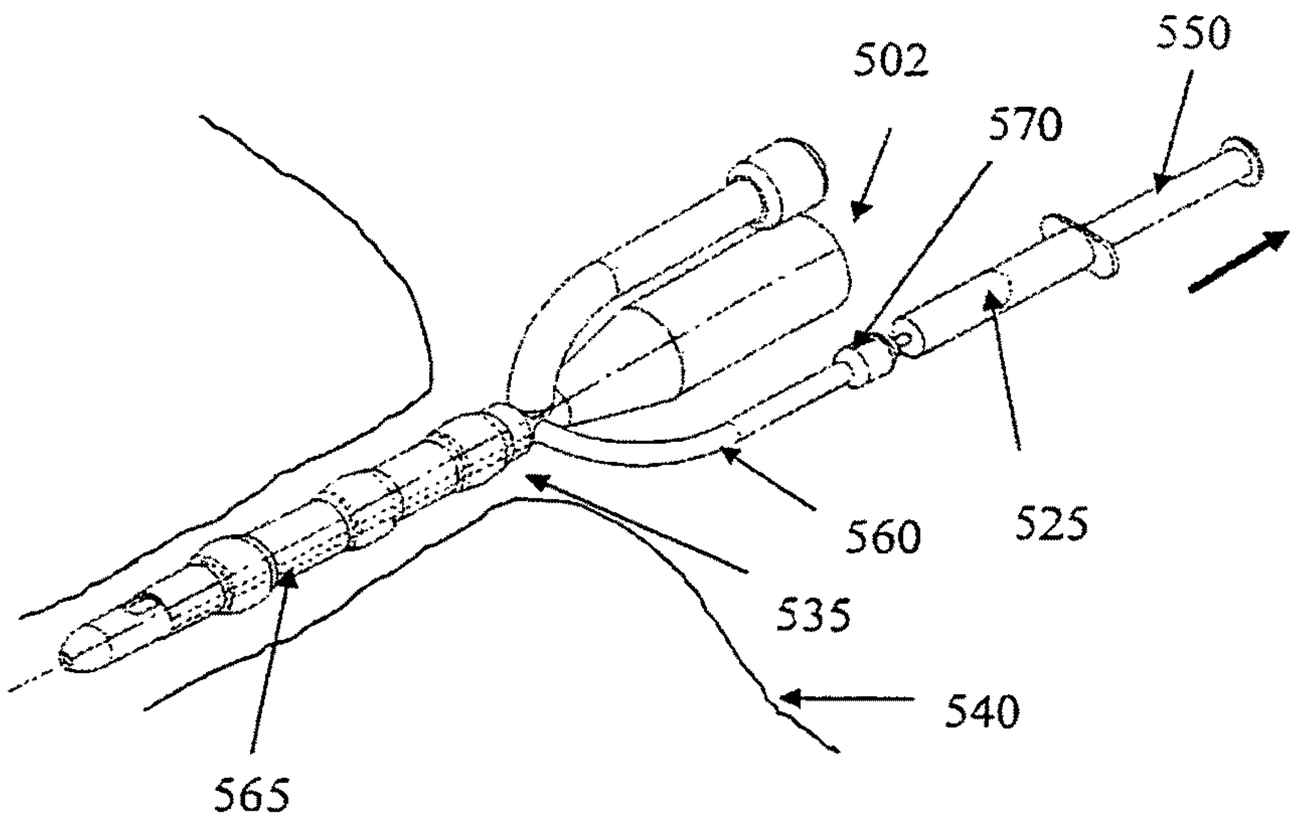


Fig 5d

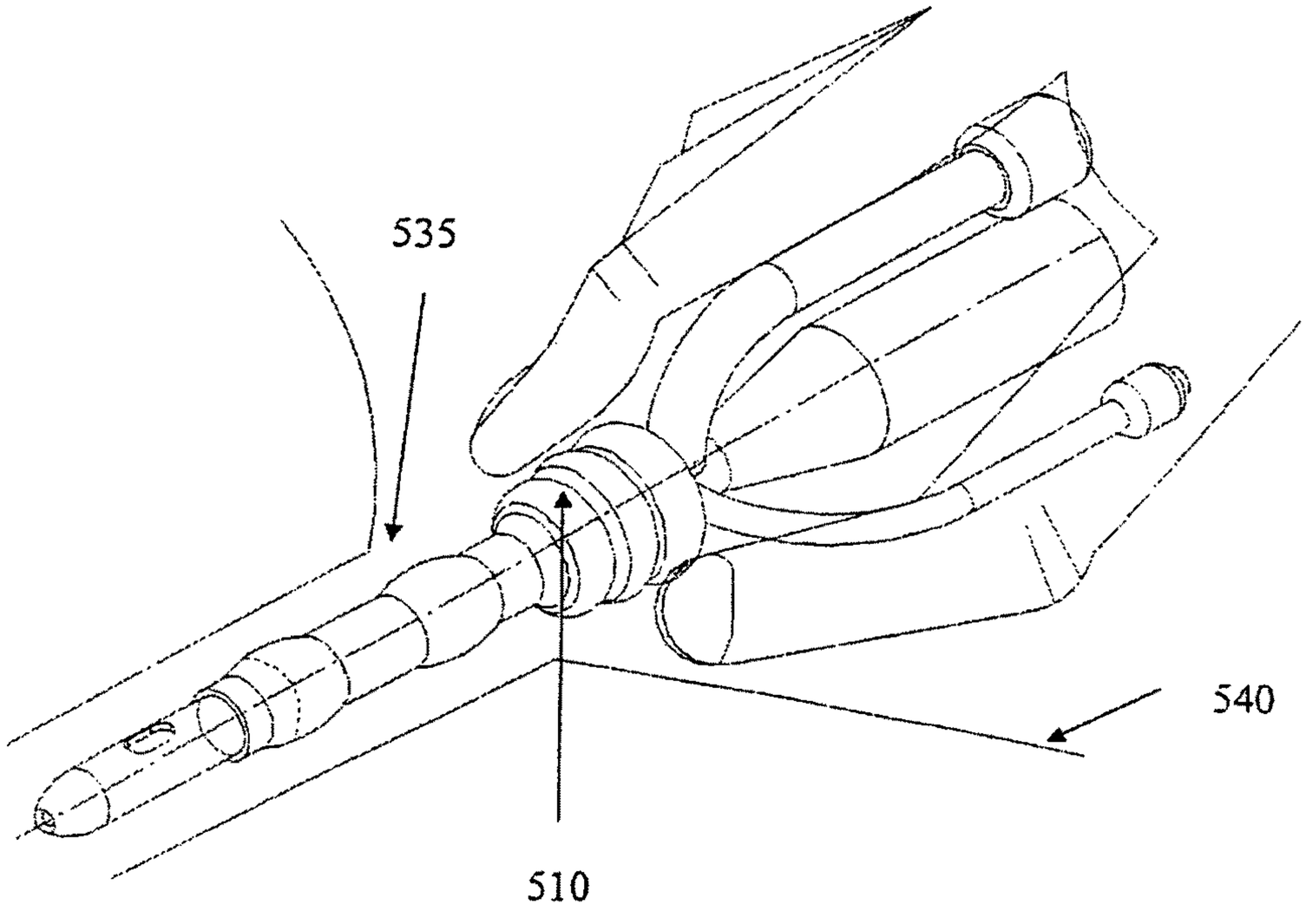


Fig.5e

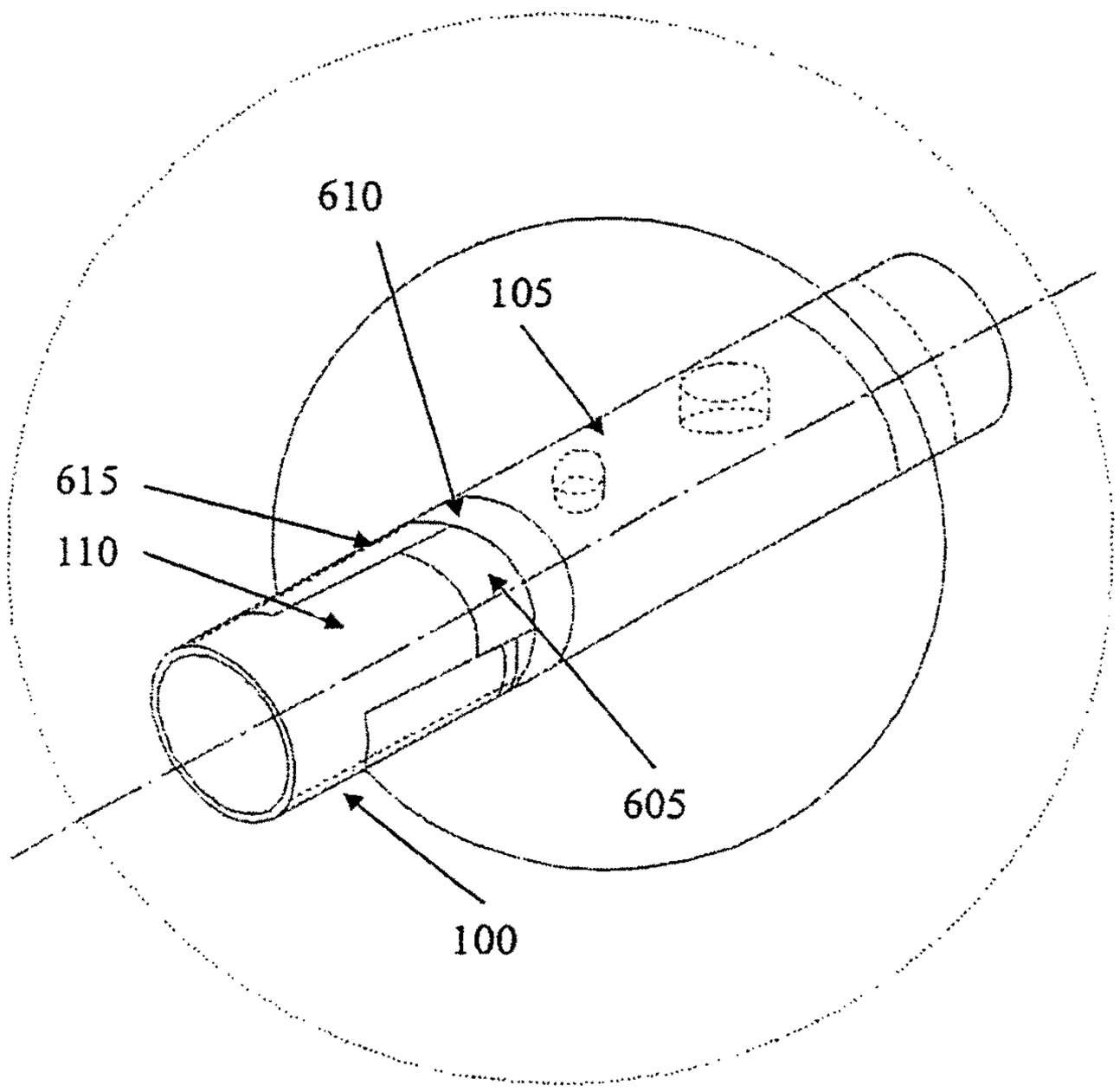
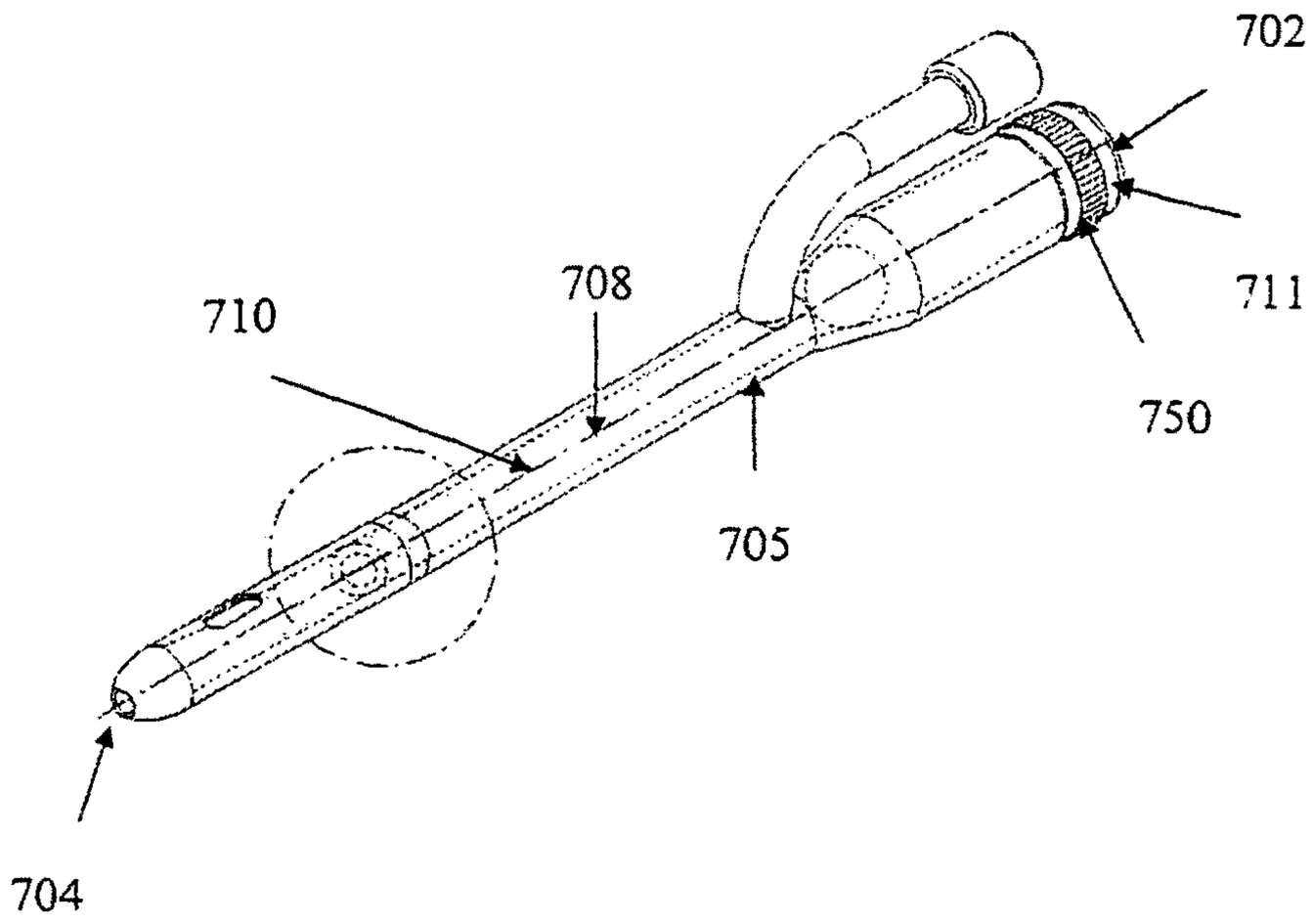


Fig 6



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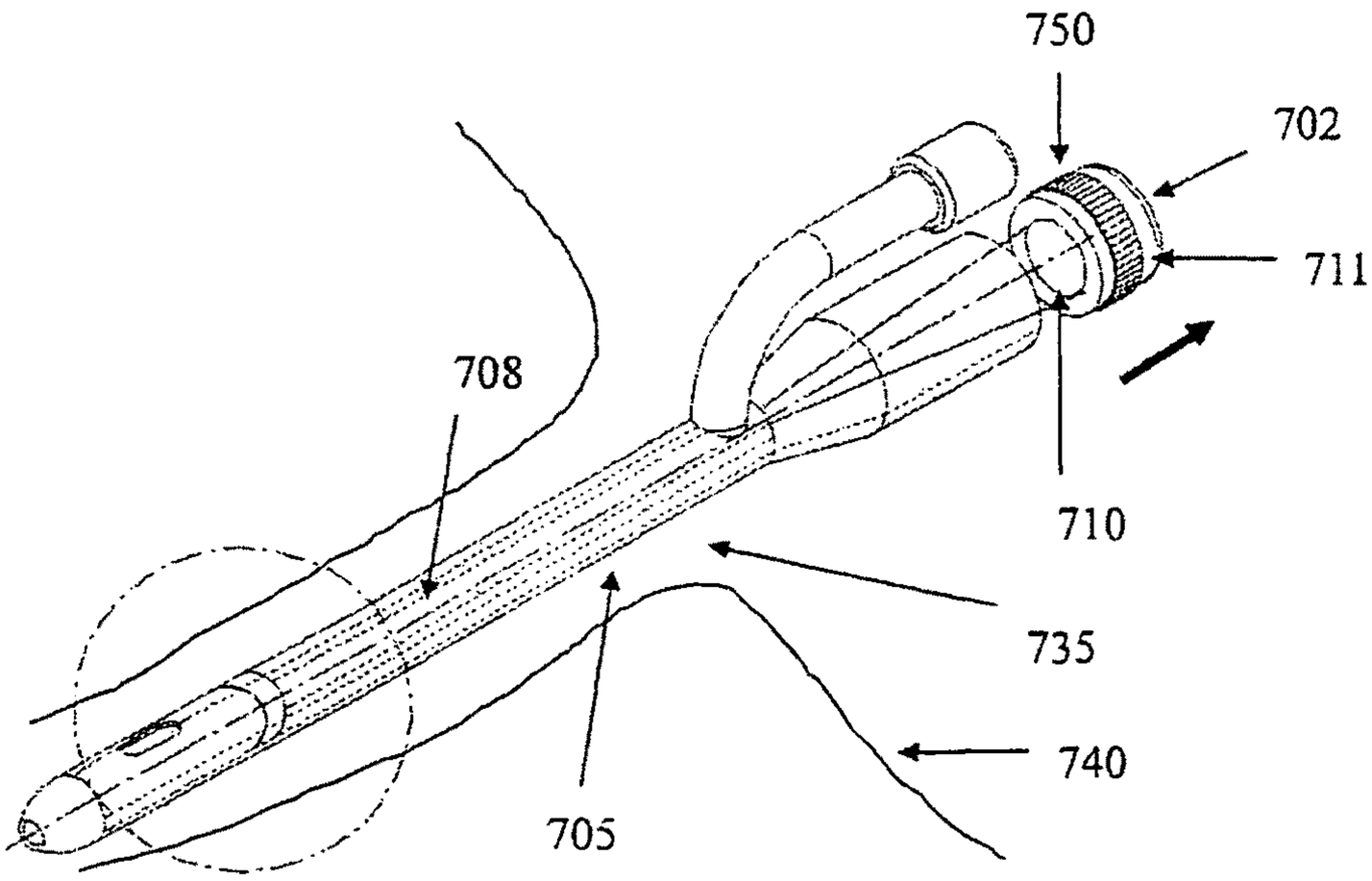
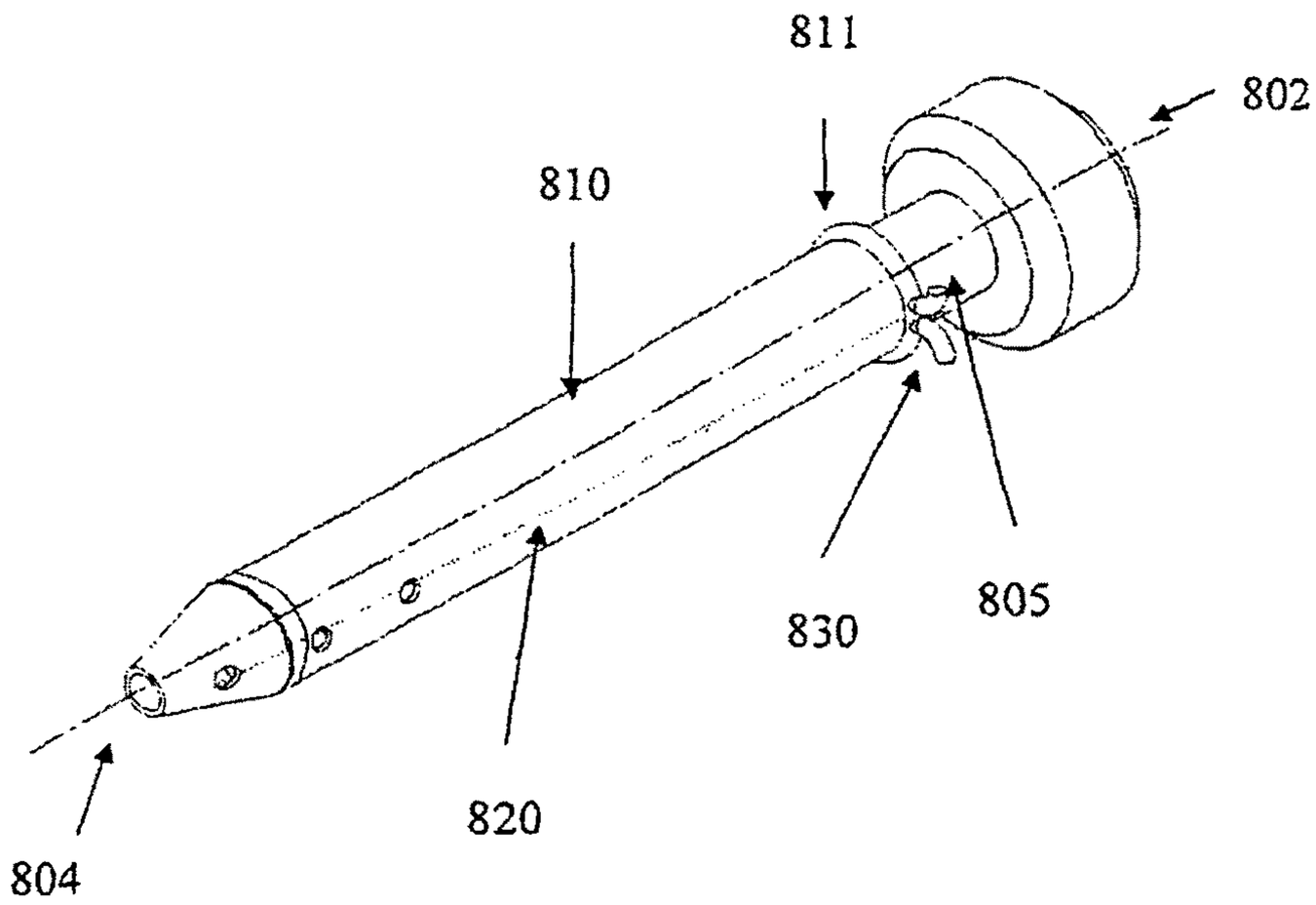


Fig.7b



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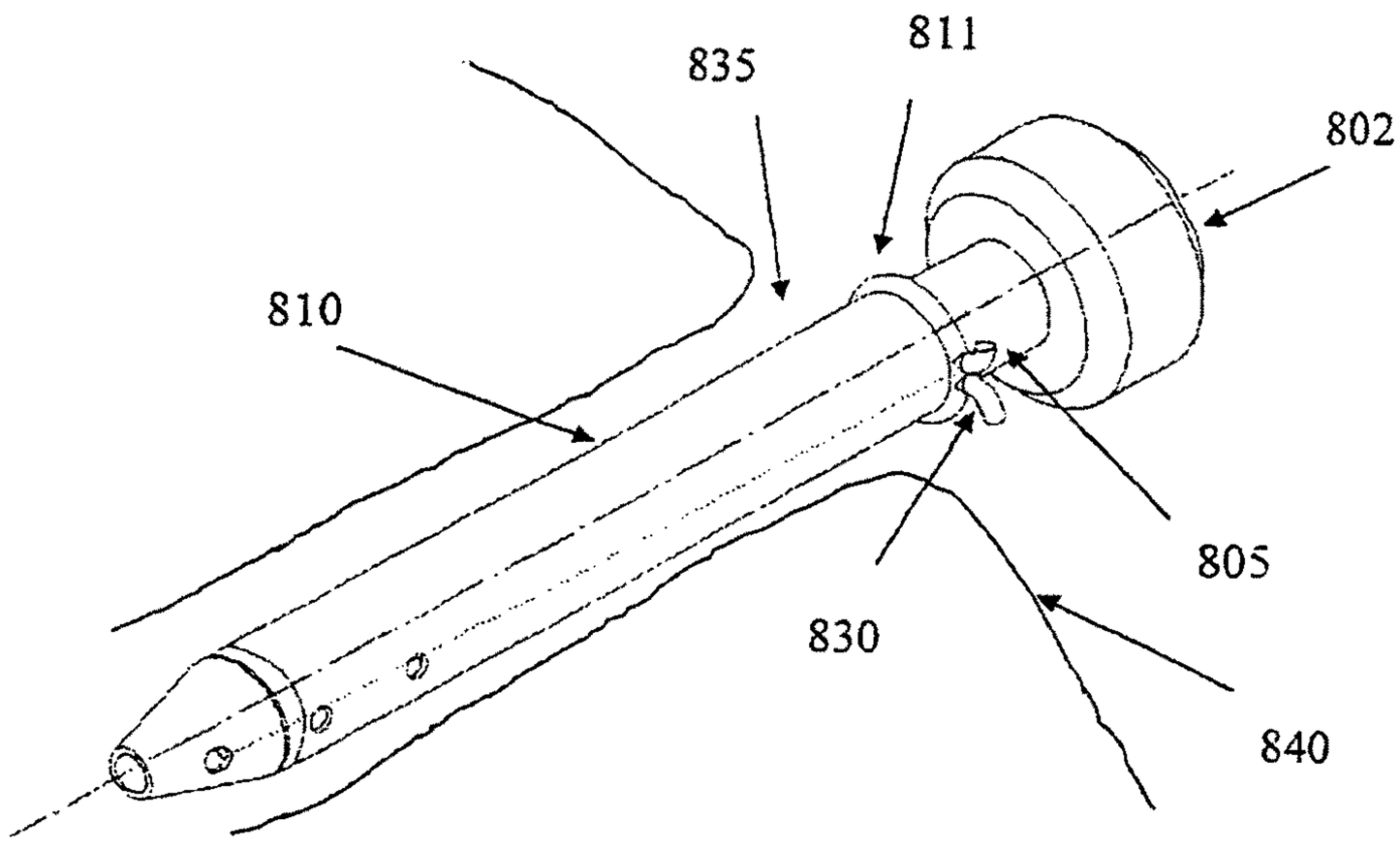

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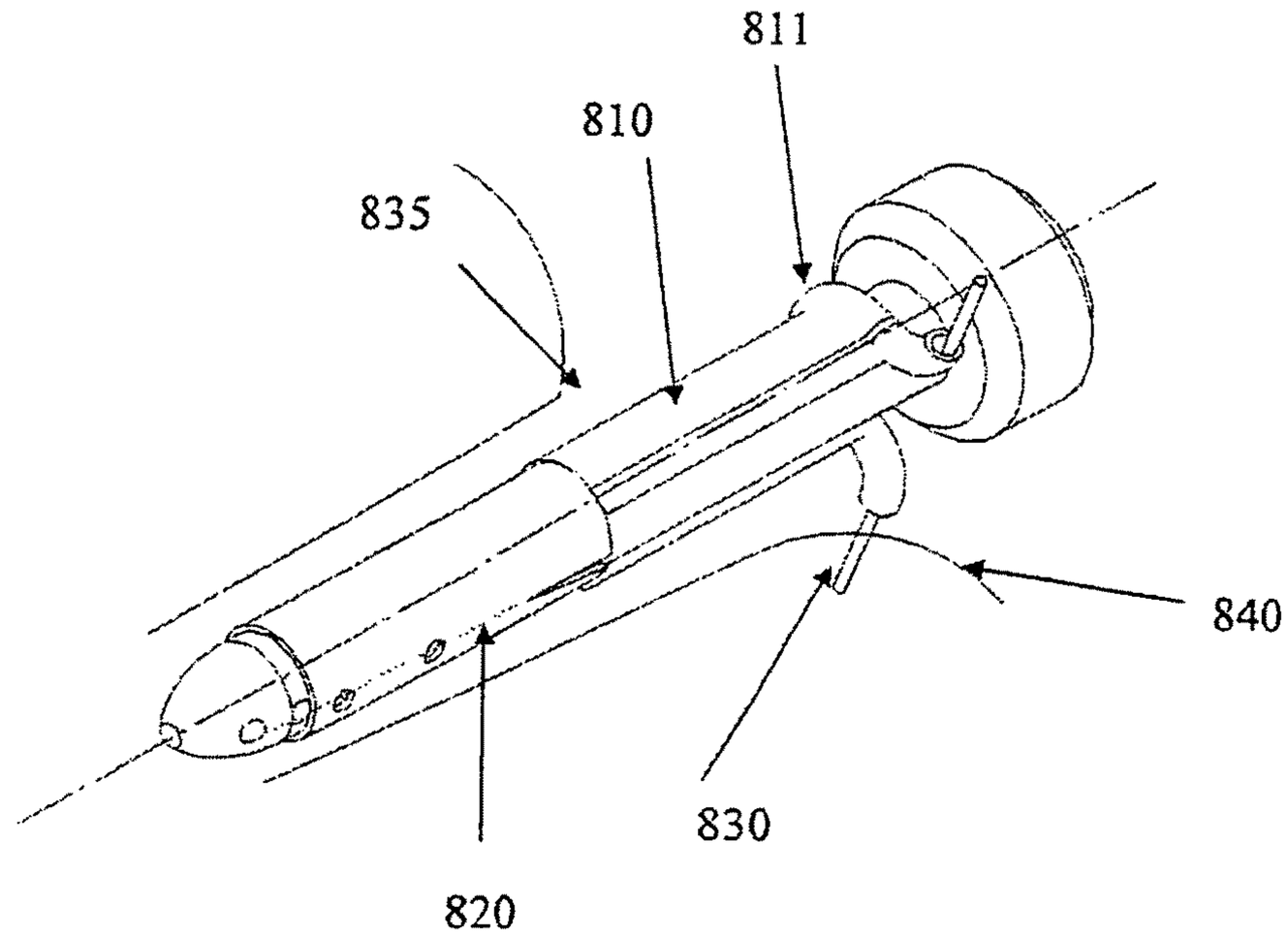

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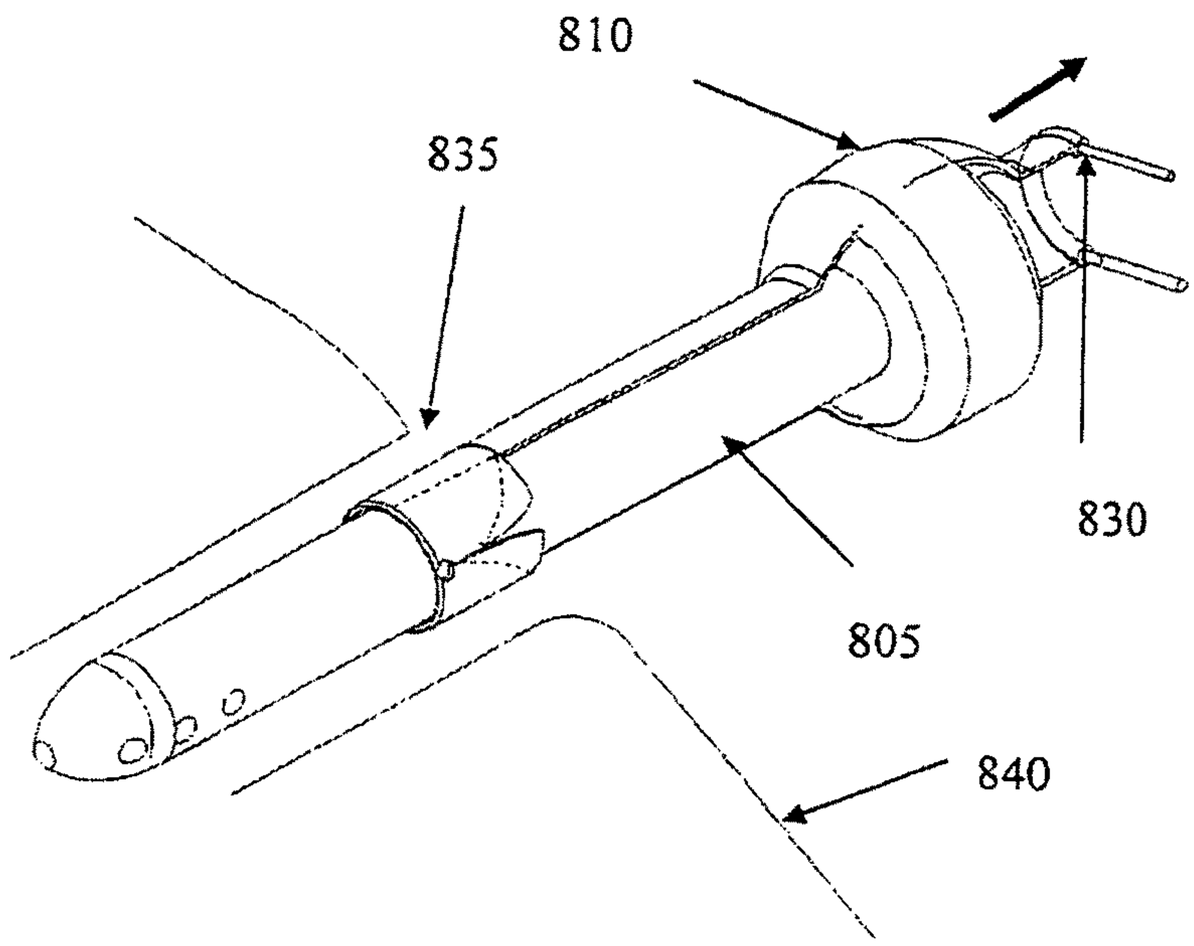

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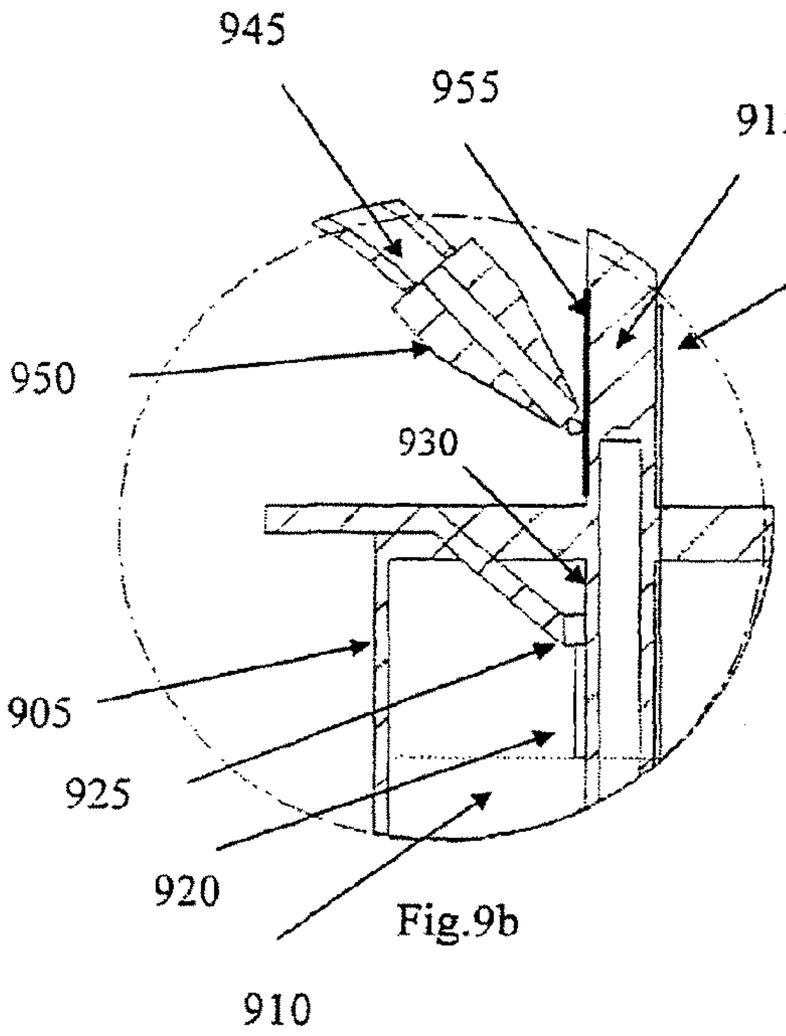

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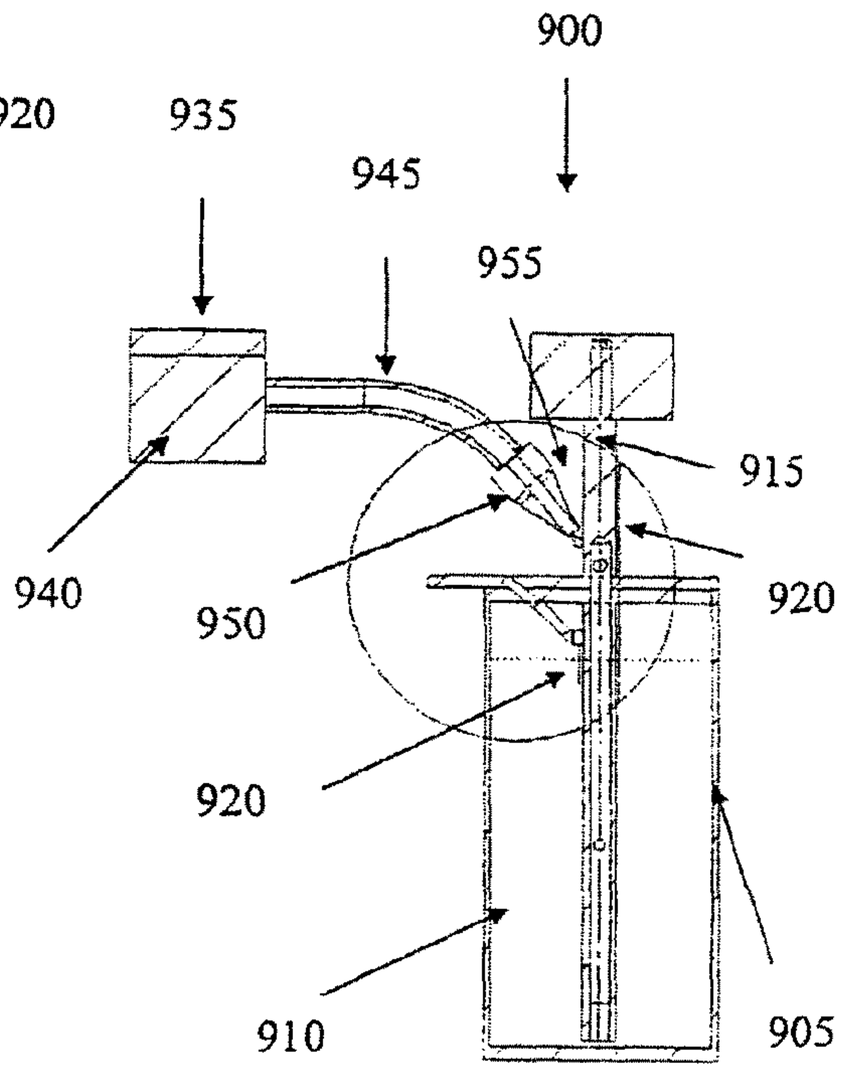

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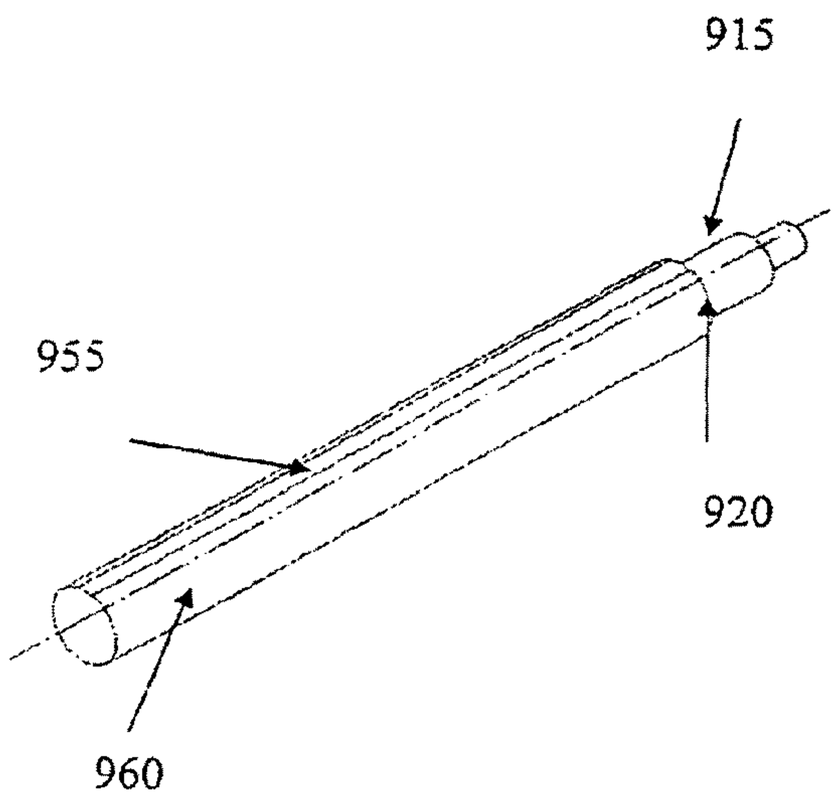

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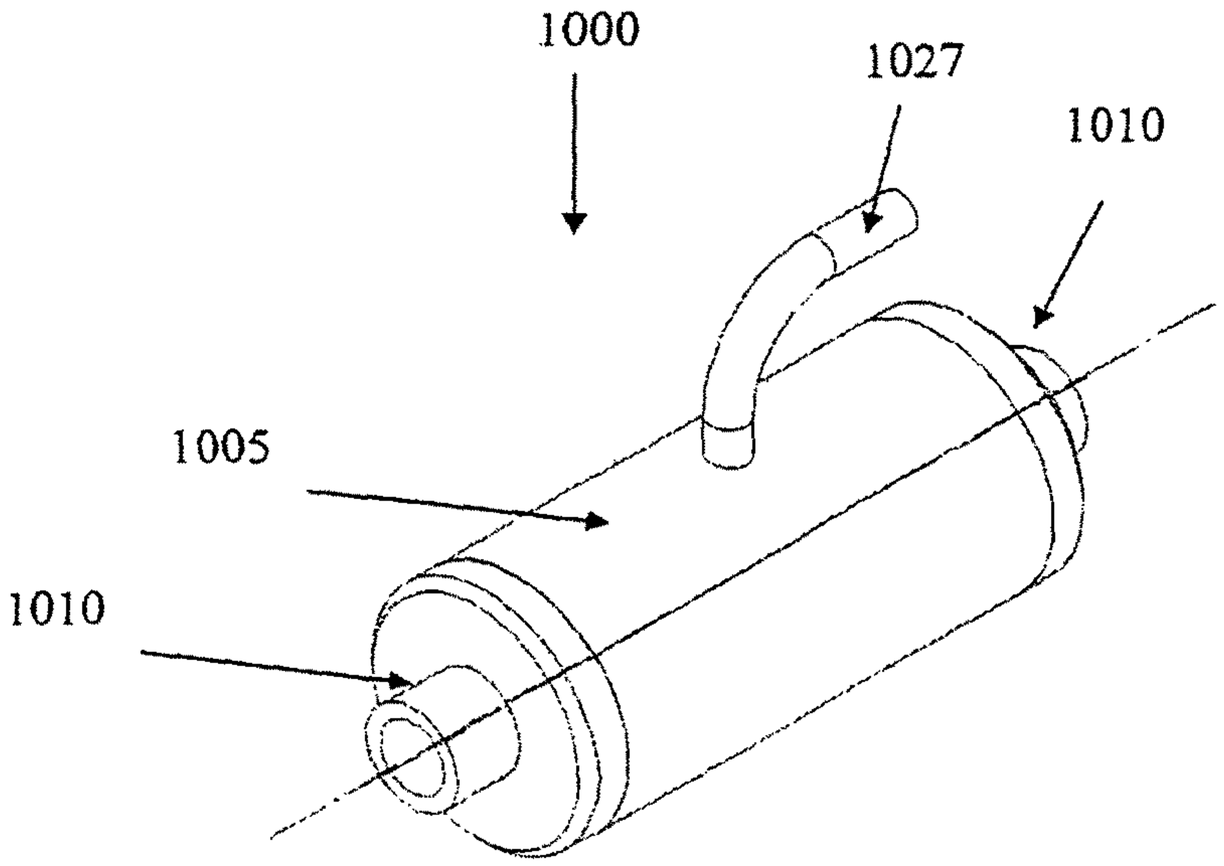

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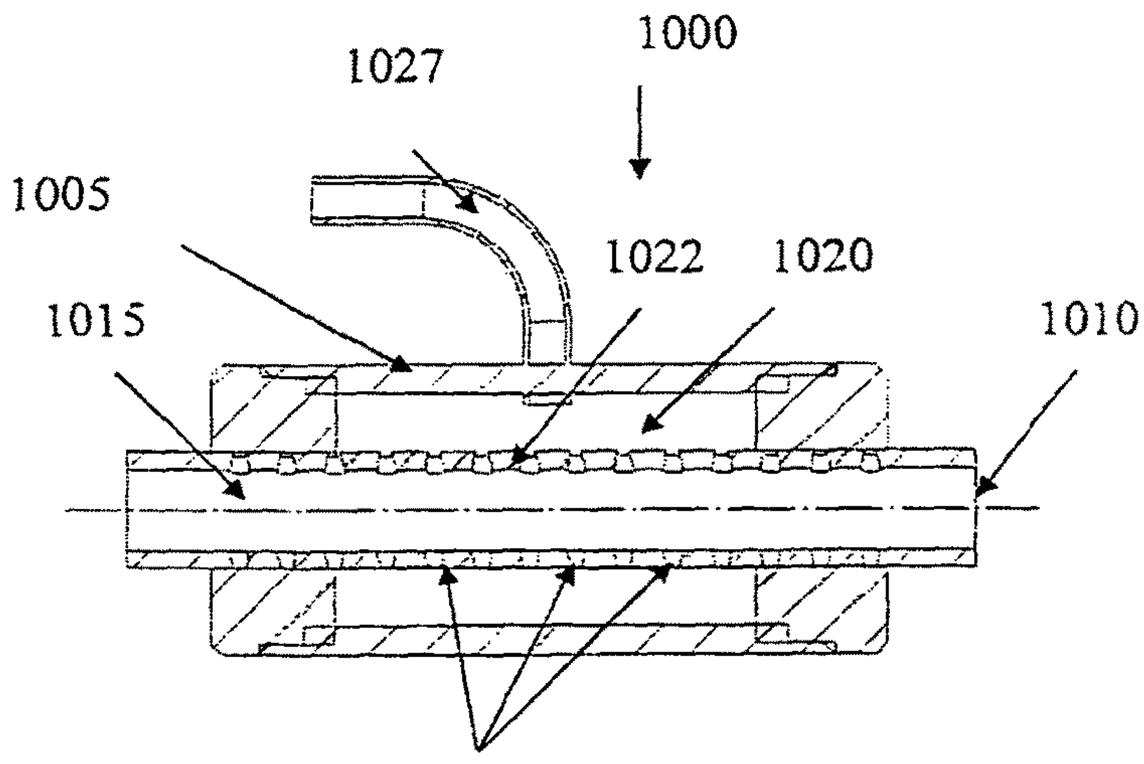

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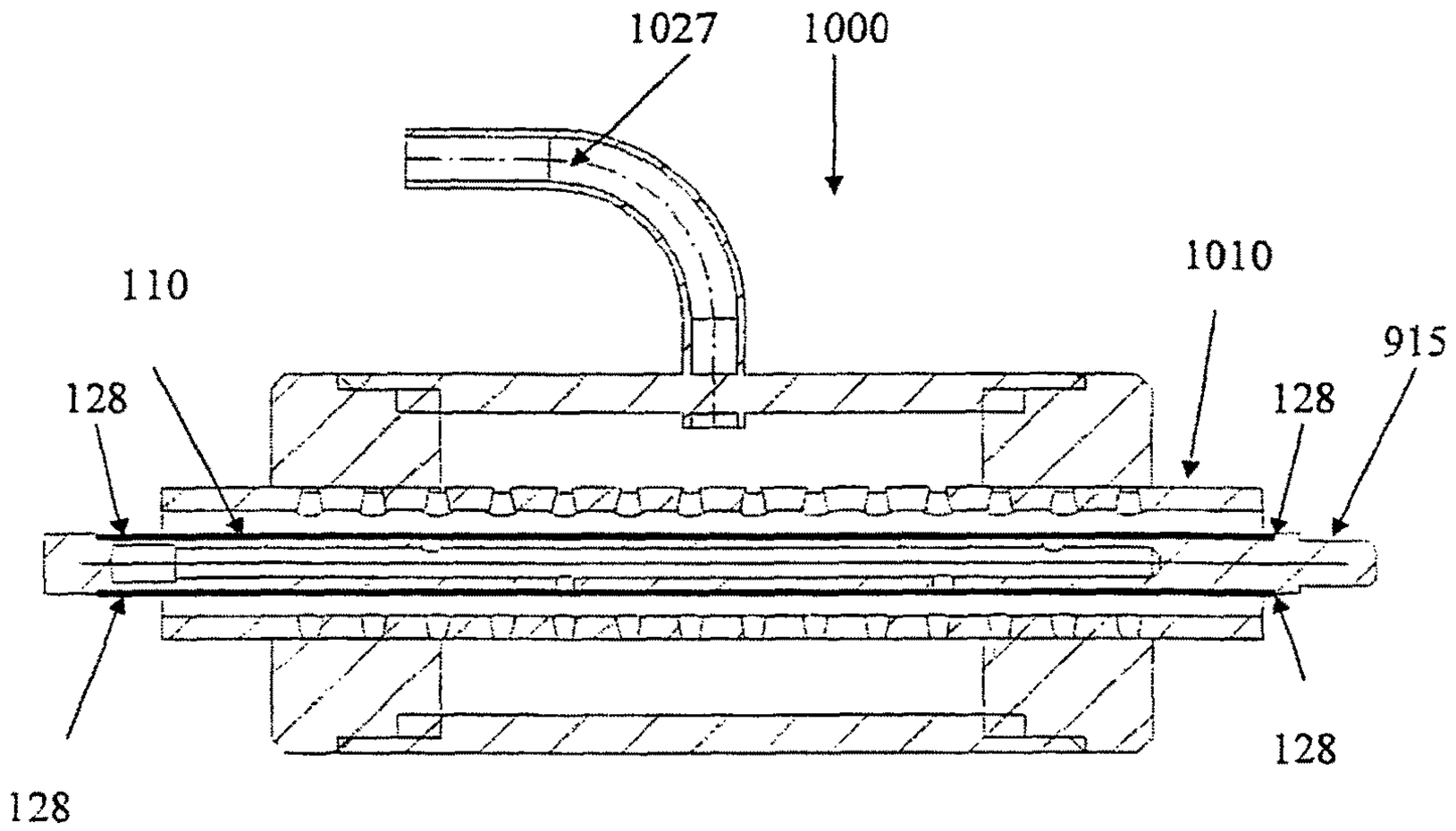

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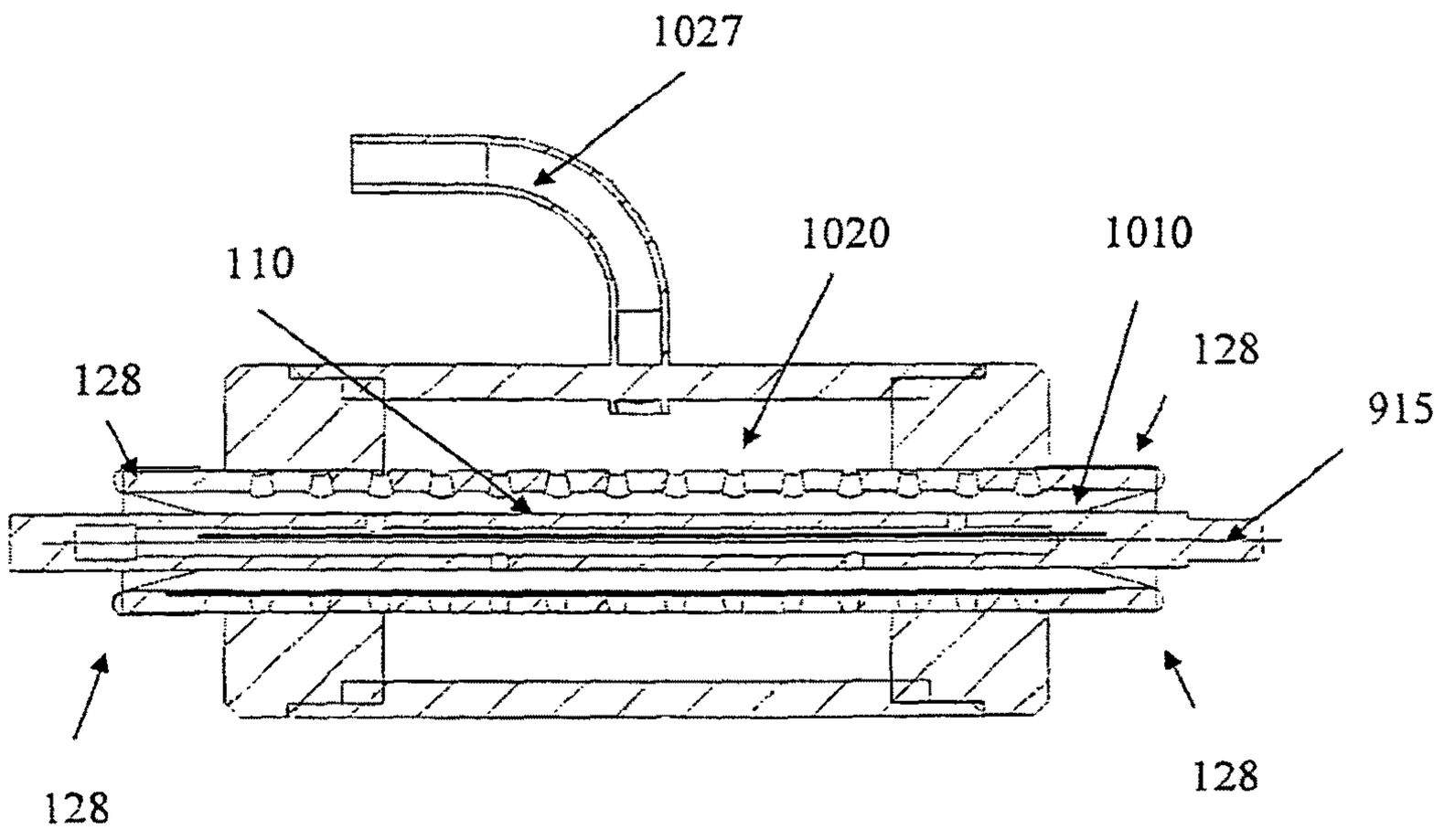

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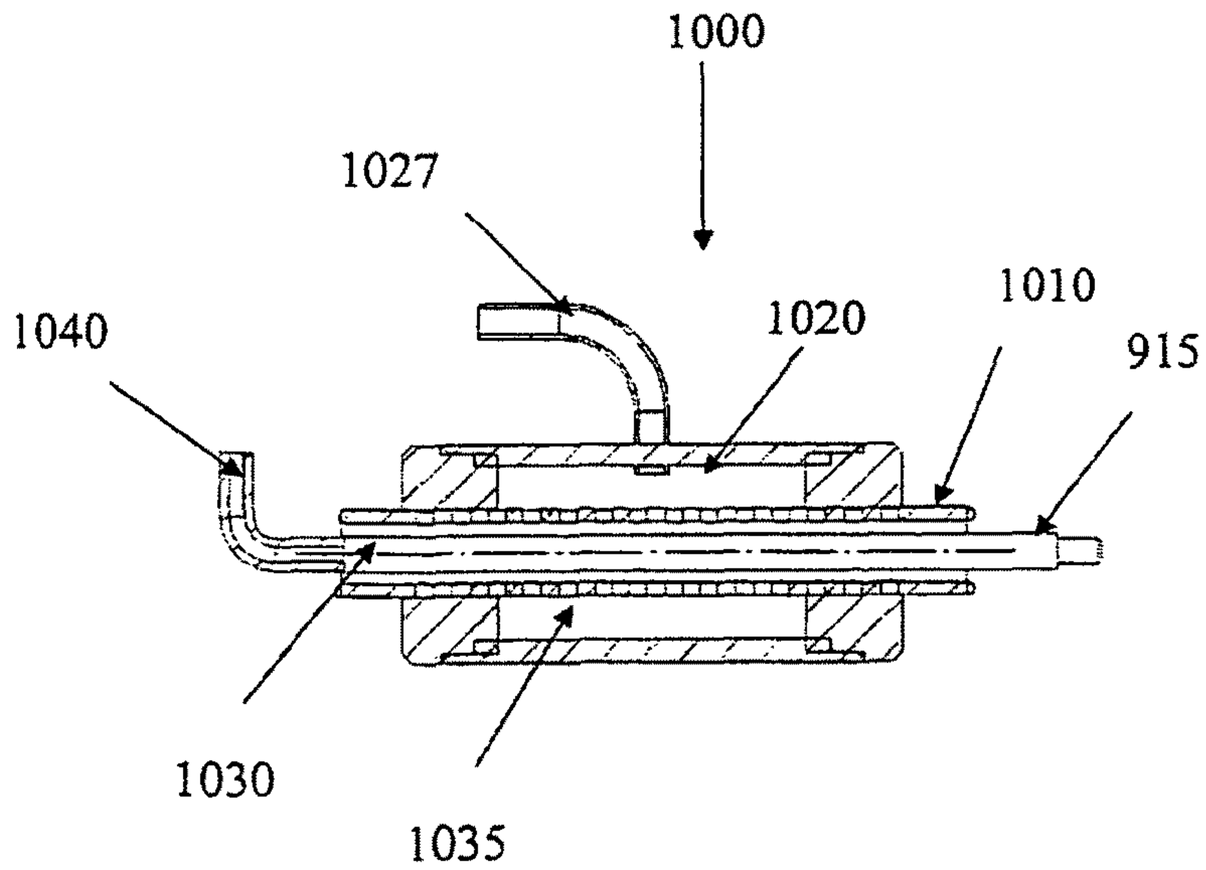

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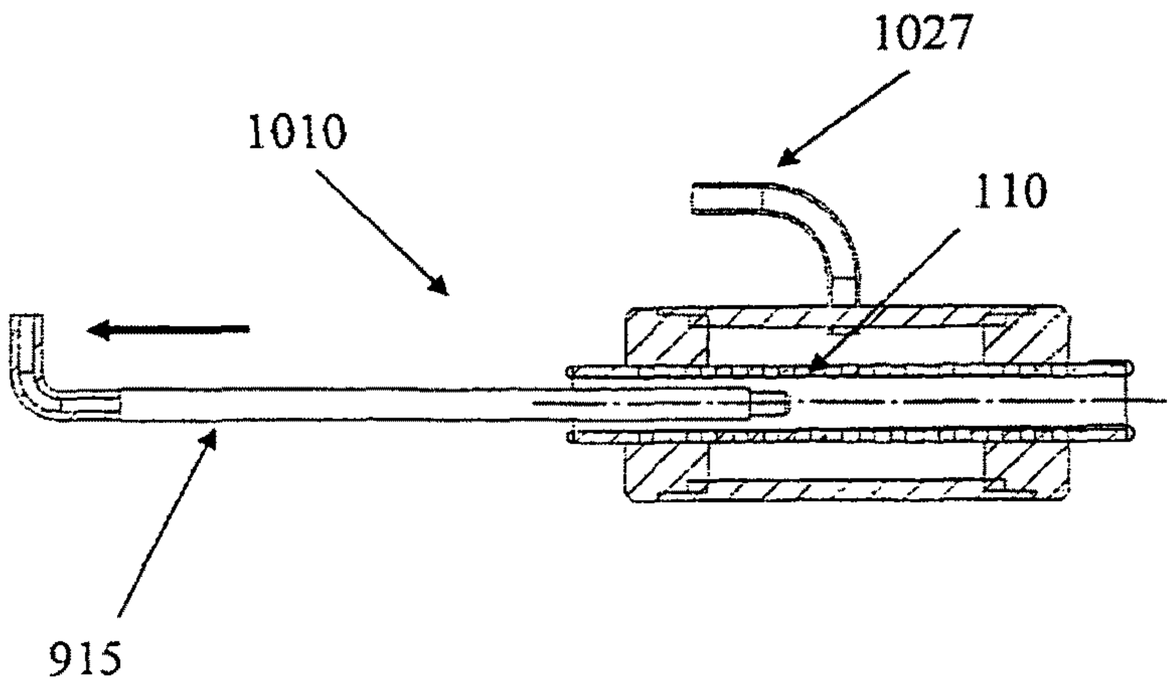

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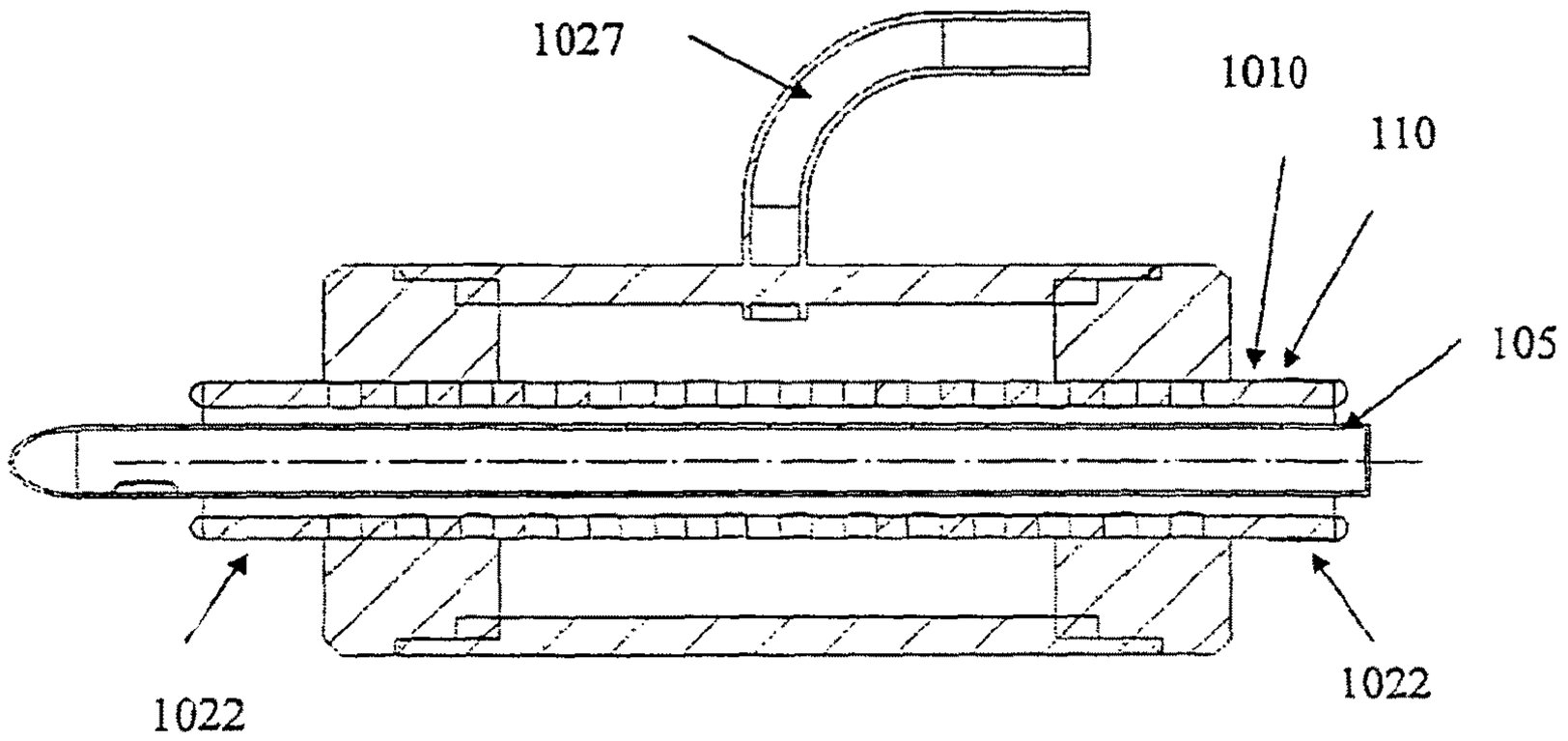

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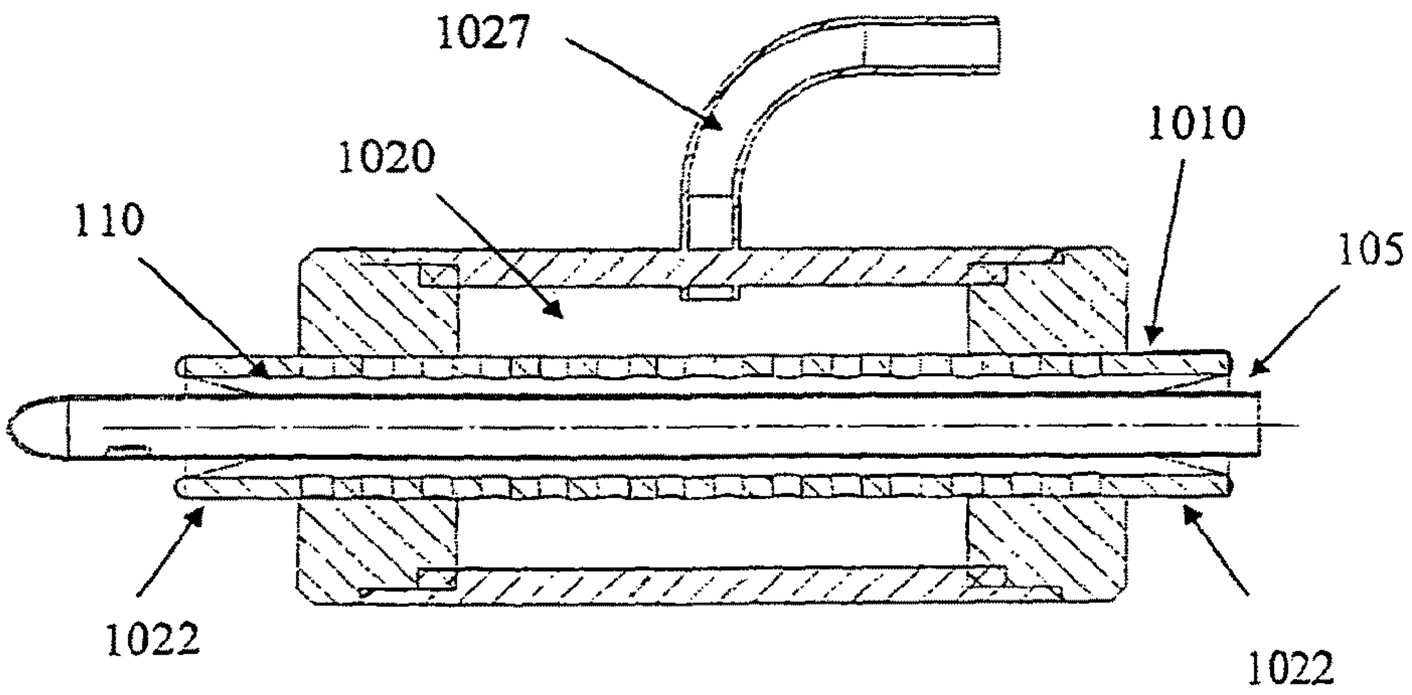

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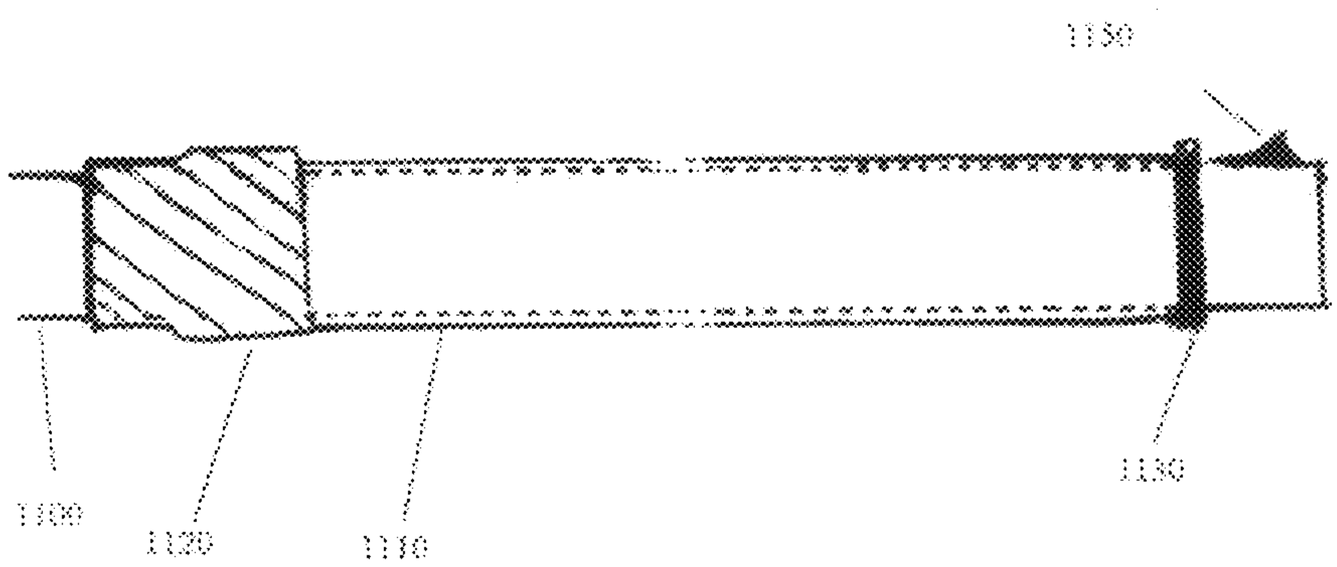
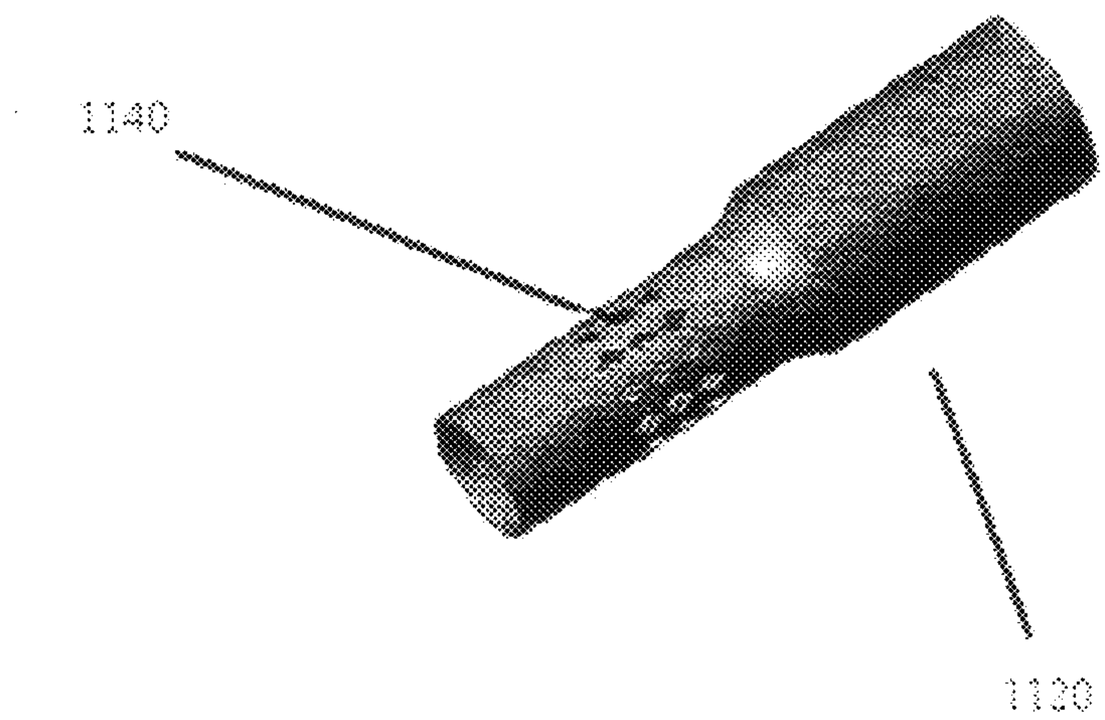


Fig. 11a



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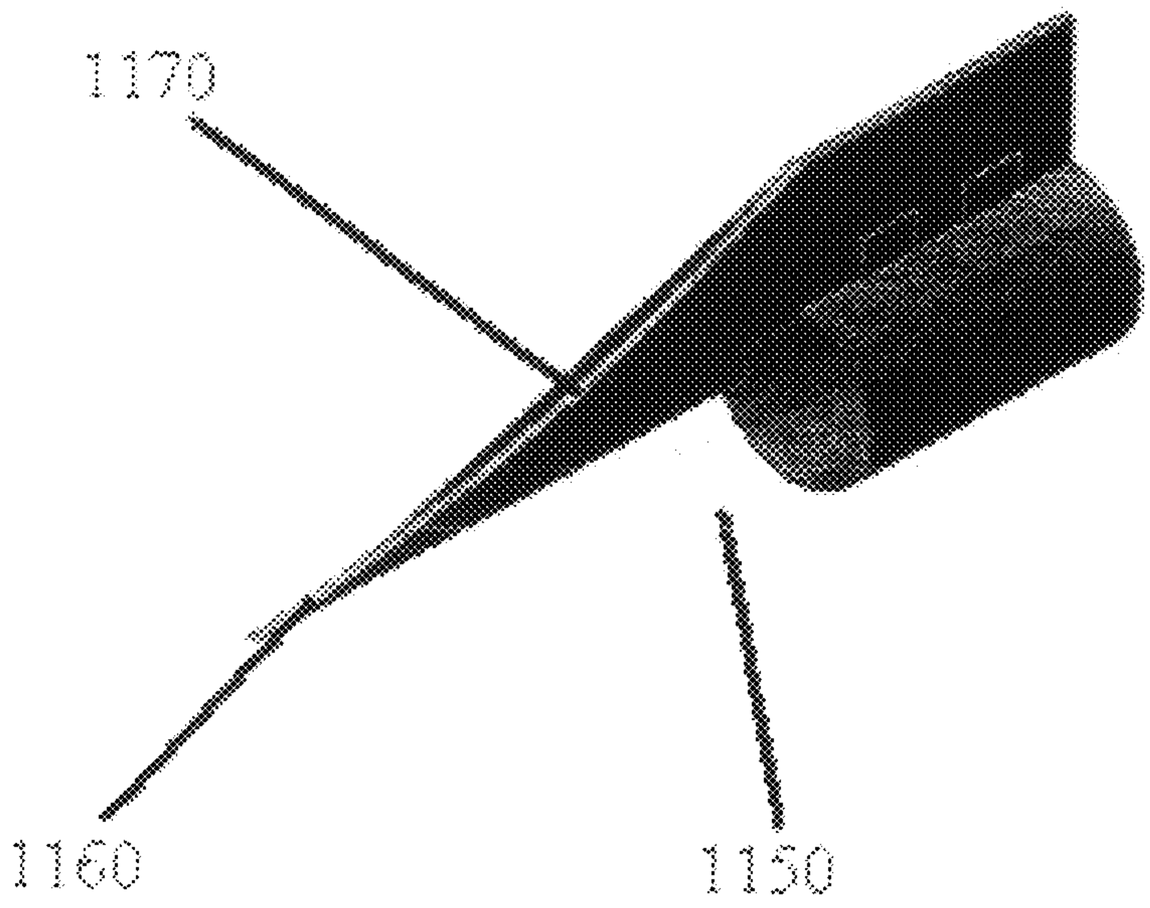

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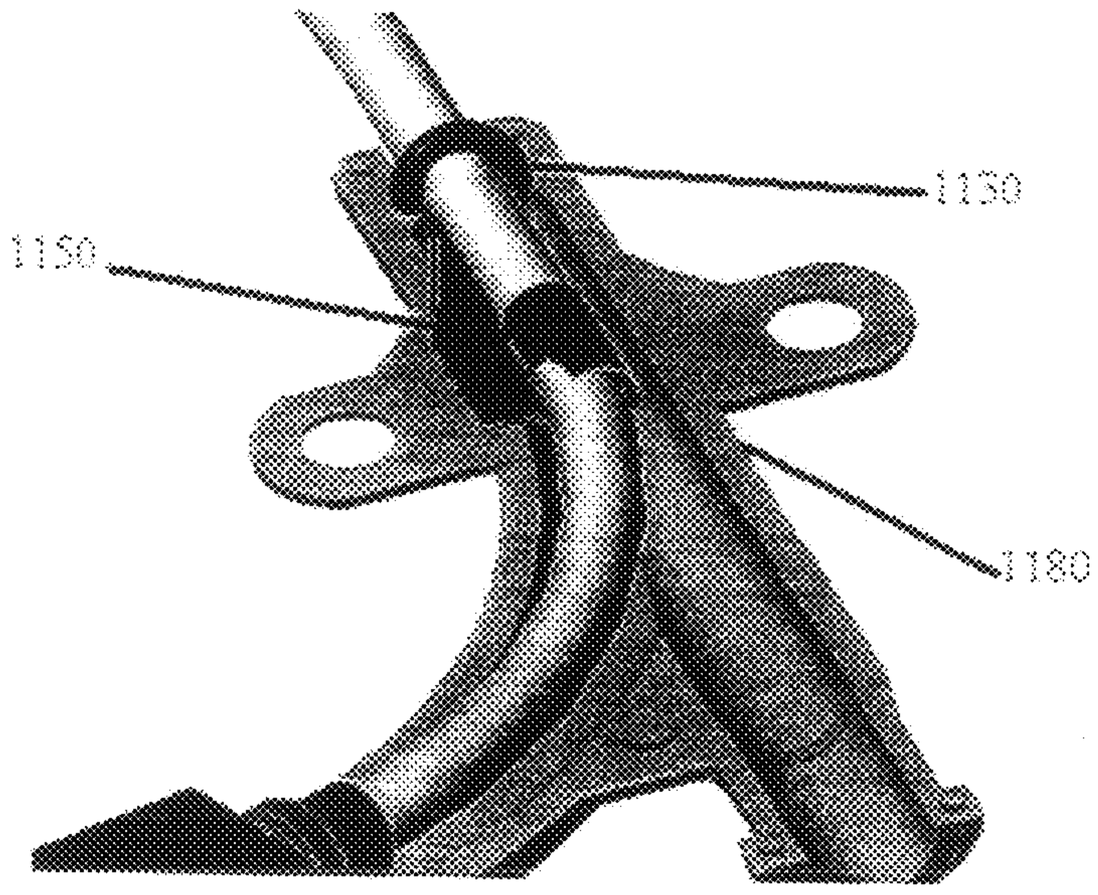

Fig. 11d

INDWELLING DEVICE

This application is a continuation of application Ser. No. 10/916,631, filed Aug. 12, 2004, now pending, that application is a continuation-in-part of application Ser. No. 10/074,017, filed Feb. 14, 2002, now abandoned, the entire contents of which are hereby incorporated by reference in this application.

FIELD OF THE INVENTION

The present invention is in the field of medical devices, and more specifically relates to indwelling medical devices.

BACKGROUND OF THE INVENTION

There are many medical devices that are inserted into the body and left indwelling for a prolonged period of time. These include, for example, various types of catheters, cannulae, drains, implants, stents, pacemakers, electrodes and other devices. Some of these devices, such as a urinary catheter, when in use, extend from the exterior of the body into the body interior, passing through an orifice on the body surface. The orifice may be a natural orifice (e.g. mouth, meatus, nostrils, etc.) or an artificial orifice (e.g. a hole formed in the skin by a surgical incision). Other indwelling devices, such as a pacemaker or stent, are completely enclosed inside the body during use. Accessing these devices typically requires surgical incising or other invasive approaches.

Although using indwelling devices is a common medical procedure, it is often limited due to formation of biofilm such as calcifications and other debris, and colonization of microorganisms, such as bacteria and fungi, on the surface of the device. This may cause inflammation and further infection around the device. The formation of biofilm and contamination is common with exposed indwelling devices, limiting the amount of time that they may be left in the body before having to be removed and possibly replaced with a new device.

Contamination of the device and tissues surrounding it may occur as the device is inserted into the body. For example, the end of a urethra closest to the meatus is naturally contaminated with various infectious agents, while the remainder of the urethra, nearer to the urinary bladder is normally sterile. During insertion of a catheter through the urethra to the urinary bladder, the catheter contacts infectious agents in the beginning of the urethra and spreads them up the urethra into the normally sterile portion and into the bladder. In order to reduce the spread of microorganisms up the urethra during insertion of a urinary catheter, it is known to first insert a hollow sheath into the beginning of the urethra that extends in the urethra to just beyond the contaminated region. A urinary catheter is then inserted through the sheath into the normally sterile part of the urethra, and into the bladder. The sheath thus intervenes between the catheter and the microorganisms in the infected part of the urethra, and thus decreases the chance of microorganisms spreading into the normally sterile portion of the urethra and into the bladder. After insertion of the catheter, the sheath is withdrawn from the body. Such sheaths are disclosed, for example, in U.S. Pat. No. 5,417,666.

Microorganisms may also migrate along an exposed indwelling device after its insertion along the outside surface of the device at its interface with the surrounding tissue. In order to inhibit the migration of microorganisms along the device, it is known to impregnate the device with antiseptic substances that are released from the catheter over time. A catheter designed to release antiseptic substances is disclosed, for example, in U.S. Pat. No. 3,598,127. Antiseptic impregnation, however, is not effective in the prevention of biofilm formation and is of very limited value in preventing infection due to the development of resistance among the microorganisms to the antibiotic.

SUMMARY OF THE INVENTION

It has now been found that it is possible to prevent the build-up of biofilm on the surfaces of indwelling medical devices by means of providing removable covers. By means of this arrangement, biofilm components become deposited on the surface of a cover instead of on the surface of the medical device itself. This cover may then be removed without disturbing the positioning or functioning of the indwelling device to which said cover was attached, thereby removing the built-up biofilm from the region of the device, and from the body. The act of removing the cover exposes either a further cover, enabling the removal process to be repeated, or, the external surface of the indwelling device itself. Unexpectedly, the inventors have found that it is possible to construct a covered device, such that the desired functioning thereof (for example the passage of fluids through a catheter or the mechanical dilatory action of a stent) is not affected or influenced by the presence of one or more covers on the surface of the device.

The term "biofilm", explained hereinabove, refers to the build-up of biologically-derived matter such as calcified material and other debris, as well as microorganisms, such as bacteria and fungi, on the surface of the device. This may cause inflammation and further infection around the device. In certain locations and in certain circumstances the biofilm and associated inflammatory processes may lead to undesirable blood clot formation.

The present invention is thus primarily directed to indwelling medical devices having an outer surface, at least a portion of which is protected by a manually detachable cover. During insertion, the cover is attached to the surface so as to prevent relative movement of the surface and the cover. This allows the integrity of the device and cover to be maintained during insertion. Once the covered device (e.g. catheter, stent, drain etc.) has been inserted into the desired operating location, said device may be manipulated or operated in the normal manner, without any hindrance or loss of functionality arising from the presence of the cover. At any time after insertion, the cover may be detached from the shaft and removed from the body, leaving the device in place. Removing the cover from the device removes the biofilm and contamination that has accumulated on the cover.

The cover is preferably made from non-allergic biocompatible materials such as natural rubber, silicone rubber, latex, woven metal mesh, parylene, polyvinylchloride, polyurethane, mylar, nylon and the like. The cover may be impermeable to body fluids or microorganisms. The cover may have a rough or smooth surface.

The covered device provided by the present invention may comprise any of the different types of indwelling medical devices known in the art. In particularly preferred embodiments, however, the medical device is selected from the group consisting of:

(a) a catheter (e.g. a urinary catheter, venous catheter, arterial catheter dialysis catheter);
(b) a cannula;
(c) a drain;
(d) a stent;
(e) a pacemaker; and
(f) an electrode.

In a preferred embodiment, the device has an outer surface that is protected by a stack of two or more sequentially detachable covers. A first, innermost, cover is in direct contact with the outer surface of the device. A second detachable cover is in contact with the first cover, so that the first cover is between the second cover and the surface. Additional covers may also be present, as required. At any time after insertion of the device into the body, the outermost cover may be detached from the surface and removed from the body, leaving the device in place with one less cover over the surface. The newly exposed outermost cover may, later on, be detached from the surface and removed from the body. This process may be repeated until all of the covers have been removed. When using multiple covers, the covers may be made from the same material as the surface of the device or from a different material. The covers may be identical or different. They may be made from different materials or the same material. The thickness of each layer may be the same or different.

A detachable cover for a device may be made using a pre-formed cover that is applied to the surface. A cover may be formed having a lumen that is dimensioned to receive the entire device, or a portion of it in the lumen. Alternatively, a liquid coating substance may be applied to the device or to a portion of its surface and allowed to solidify by curing, polymerizing, or drying. For example, a 2:1 solution of silicone rubber:toluene may be applied to the surface and allowed to dry and cure. The coating substance may be applied to the device or an outermost detachable cover previously applied to the surface, for example, by brushing, immersion, spraying, or any other method of deposition.

Two adjacent members (a detachable outermost cover and the surface of the device, or two adjacent detachable covers on a multiple coated device), may be reversibly attached to each other by any known method. For example, an adhesive may be introduced between the members and allowed to cure. The bond formed by the adhesive is subsequently broken when desired, for example, by applying an axial or radially outward force to the outermost member so as to break the bond. Alternatively, the bond may be broken by introducing a fluid between the members that breaks the bond either chemically or mechanically. As yet another alternative, the bond may be broken over time, either spontaneously or during prolonged contact of the adhesive with body fluids such as blood plasma or urine.

The reversible attachment of the two adjacent members may extend along the entire contact area between the members, or only at specific regions between the members. For example, one or more clips may be disposed on the device that presses the outermost cover to the underlying member at various locations. The clips may be formed, for example, by a rubber ring that may be rolled onto the outermost layer. The outermost layer is detached by cutting the ring or by rolling it off the outermost layer. The clip may be a toroidal balloon that constricts the members when inflated and releases the attachment when deflated.

A detachable cover may be made from an elastic material. An elastic cylinder may be stretched over the shaft of a catheter or over detachable covers already present on the shaft and allowed to contract with the shaft and any previously existing detachable covers in its lumen. In this case, a reversible attachment is formed between the new cover and an adjacent member by the elastic forces of the new outermost cover. The attachment may be broken by making a longitudinal cut along the outermost cover. The cover may have one or more lines of preformed perforations that are easily torn by splaying apart an end of the coating.

The mechanical removal of the detachable cover(s) may also be achieved by means of the use of a fixed, proximally-located knife blade. This blade is shaped and disposed such that the proximal end of the outermost cover may be pulled towards the blade, and subsequently split longitudinally by the action of the stationary blade on the proximally-drawn cover. In this manner, the apposition and attachment of the outermost cover to the adjacent cover or external surface of the indwelling device is disrupted, thus allowing the removal of said outermost cover from said device and from the body.

The space between the device and a cover or between two adjacent covers may contain material to reinforce the attachment or to enhance relative sliding. The material may repel deposits, and/or contain pharmaceutically-active agents, including but not limited to anti-microbial agents such as antibiotics. The interface material can be the same or different, for each pair of adjacent members. For example, mineral oil may be present to enhance sliding and prevent penetration of contamination between the members.

In a particularly preferred embodiment of the device of the present invention, sealing elements are present at the distal and/or proximal extremities of the covered device. The presence of these sealing elements prevents the ingress of liquids such as blood, urine, tissue fluid and so on into the space between pairs of adjacently-disposed covers or into the space between the innermost cover and the external surface of the medical device itself.

In another aspect, the present invention is also directed to indwelling medical devices having an inner or luminal surface, at least a portion of which is protected by either one manually detachable cover or a stack of two more sequentially detachable covers. This particular embodiment of the device of the invention is particularly suitable for use in applications where it is desirable to prevent the formation and growth of blood clots on the luminal surface of indwelling devices such as venous and arterial catheters. During insertion, the cover is attached to the surface so as to prevent relative movement of the surface and the cover. This allows the integrity of the device and cover to be maintained during insertion. Once the covered internal device (e.g. internal surface of a catheter or drain) has been inserted into the desired operating location, said device may be manipulated or operated in the normal manner, without any hindrance or loss of functionality arising from the presence of the cover. At any time after insertion, the cover may be detached from the shaft and removed from the body, leaving the device in place. Removing the cover from the device removes any blood clots, contamination and other biofilm deposits that may have accumulated on the cover. All of the various different embodiments and technical features described above in relation to the devices having external covers also apply to the devices having internal covers as described immediately hereinabove.

In a further aspect, the present invention also provides a method for preventing biofilm buildup on the surface of an indwelling medical device that has been inserted into the body of a subject, said method comprising the steps of:

a) providing a medical device fitted with a detachable cover attached to at least a portion of its outer surface, such that the presence of said cover does not interfere with the intended function of said device;

b) inserting said device together with its attached cover into the body of the subject;

c) detaching the cover from the outer surface of the medical device and removing said cover from the body together with any biofilm deposited on the surface of said cover, while leaving the device inside the body such that it may continue to fulfill its intended function.

The present invention also provides a further method for preventing biofilm buildup on the surface of an indwelling medical device that has been inserted into the body of a subject, said method comprising the steps of:

a) providing a medical device fitted with a stack of two or more sequentially detachable covers, such that the innermost cover is attached to at least a portion of its outer surface, and wherein the presence of said stack of covers does not interfere with the intended function of said device;

b) inserting said device together with its attached cover into the body of the subject;

c) detaching the outermost cover from the stack of sequentially detachable covers and removing said cover from the body together with any biofilm deposited on the outer surface thereof, while leaving the device inside the body such that it may continue to fulfill its intended function;

d) subsequently repeating step (c) for the one or more remaining outermost covers.

In a preferred embodiment of the above-disclosed methods for preventing biofilm buildup on the surface of an indwelling medical device, said device is selected from the group consisting of:

(a) a catheter;

(b) a cannula;

(c) a drain;

(d) a stent;

(e) a pacemaker; and

(f) an electrode.

In one particularly preferred embodiment of the method of the present invention, the device is a urinary catheter. In another particularly preferred embodiment, the device is a venous catheter. In a further particularly preferred embodiment, the device is a dialysis catheter.

All the above and other characteristics and advantages of the present invention will be further understood from the following illustrative and non-limitative examples of preferred embodiments thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

FIGS. **1***a*-**1***d* show an indwelling device having a tearable cover in accordance with one embodiment of the invention;

FIGS. **2***a*-**2***c* show an indwelling device having a cutable cover in accordance with another embodiment of the invention;

FIGS. **3***a*-**3***d* show an indwelling device having a rollable cover in accordance with another embodiment of the invention;

FIGS. **4***a*-**4***c* show an indwelling device having a helical cover in accordance with another embodiment of the invention;

FIGS. **5***a*-**5***e* show an indwelling device having a cover attached with internal balloons in accordance with another embodiment of the invention;

FIG. **6** shows use of a clamp securing the distal end of a cover to a surface;

FIGS. **7***a* and **7***b* show an indwelling device having a cover attached on an inner surface;

FIGS. **8***a*-**8***d* show an indwelling device having a tearable cover in accordance with another embodiment of the invention;

FIGS. **9***a*-**9***c* show a system for preparing a cover on a mandrel in accordance with one embodiment of the invention; and

FIGS. **10***a*-**10***h* show a system for transferring a cover from a mandrel onto a device.

FIGS. **11***a*-**11***d* show an indwelling device having a cover attached to its outer surface, said cover being fitted with proximal and distal sealing elements and a fixed cutting blade.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The invention will now be described by non-limiting embodiments. For the sake of clarity, the invention is exemplified by devices having a slender shaft such as catheters, cannulae, and drains. This is by way of example only, however, and the invention is not limited to such devices. Other devices having detachable covers are included within the scope of the invention, such as implants, stents, and pacemakers.

First Embodiment

FIG. **1***a* shows an indwelling device **100** in accordance with a first embodiment of the invention. The device **100** has a proximal end **102**, a distal end **104**, and a cylindrical shaft **105** that may be solid or hollow. The shaft **105** is contained in an outer cover **110** having the general shape of a thin cylindrical shell. The outer cover **110** is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft **105**, and allowed to contract on the shaft **105**. The outer cover **110** is reversibly attached to the shaft **105** by circumferential elastic forces in the outer cover **110** that are exerted on the shaft **105**. This prevents slipping of the outer cover **110** over the shaft **105** during insertion of the device **100** into the body, and maintains the outer cover **110** on the shaft **105** after insertion.

The outer cover **110** is formed from two materials. The first material is used to form the cover except in a narrow strip **125** that is formed from a second material. The two materials are joined at two parallel seams **120***a* and **120***b* extending along the length of the outer cover **110**. The strip of **125** formed from the second material preferably extends circumferentially for less than one quarter of the circumference of the outer cover **110**. The first material has a relatively high tear stress, for example, a silicone rubber having a tear stress of 25 to 50 kN/M. The second material is a material having a relatively low tear stress, such as a silicone rubber with a tear stress of less than 5 kN/M. The preparation of silicone rubbers and other materials having a particular tear stress are known in the art.

Between the shaft **105** and the outer cover **110** is a cord **130**. The cord is attached at one of its ends to the distal end of the strip **125**. At its other end, the cord extends beyond the proximal end of the coating. A ring **150** holds the end of cord **130** on the shaft **105**. As shown in FIG. **6**, the device **100** may optionally comprise a distally located annular clamp **610** that secures the distal end of the outer cover **110** to the shaft **105** and prevents debris from accumulating under the distal end of the outer cover **110** during insertion.

FIG. **1***b* shows the catheter of FIG. **1***a* after insertion into the body. The catheter **100** was inserted into the body through a hole **135** on the body surface **140**. The hole **135** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the

cord **130** extends through the hole **135** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord **130**. Relative movement of the shaft **105** and the outer cover **110** is prevented during insertion due to the circumferential elastic forces of the outer cover **110** on the shaft **105**.

At any time after insertion, the outer cover **110** may be detached from the device **100** by removing the ring **150** and pulling the distal end of the cord **130**. Pulling the cord **130** away from the body draws the distal end of the strip **125** into the space between the coating **110** and the shaft **105**, tearing the distal ends of the seams **120***a* and **120***b*. (FIG. **1***c*). As the cord **130** continues to be pulled, tearing of the seams **120***a* and **120***b* progresses from the distal end towards the proximal end, until the entire strip **125** has been detached from the rest of the layer **110** and removed from the body (FIG. **1***d*). This detaches the outer cover **110** from the shaft **105**. The proximal end of the torn outer cover **110** may now be grasped and manually removed from the body leaving the device **100** in place. If after removal of the outer cover **110**, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

FIG. **9** shows a system, generally indicated by **900**, for preparing the cover **110**. A reservoir **905** contains a first liquid suspension **910** for preparing the first material in the cover **110**. A cylindrical mandrel **915** is used upon which the cover **110** is to be formed. The mandrel **915** has a diameter corresponding to the inner diameter of the cover **110**. A length of the mandrel **915** is submerged in the suspension **910**. As the mandrel **915** is withdrawn from the suspension **910**, a layer **920** of the first material coating the mandrel is formed.

A wiper blade **925** is used to remove a portion of the coating **920** as the mandrel **915** is withdrawn from the suspension **910**. Above the wiper **925**, a narrow strip **930** of the surface of the mandrel **915** thus becomes exposed.

A second reservoir **935** contains a second suspension **940** that is used to form the second material of the coating **110**. The second suspension **940** is delivered to the surface of the mandrel **915** through a tube **945**. A nozzle **950** applies the second suspension to the exposed strip **930** of the mandrel **915** surface, as the mandrel **915** is withdrawn from the first suspension **910**. The second suspension **940** thus forms a coating **955** on the mandrel **915** in the exposed strip **930** created by the wiper **925**.

FIG. **9***c* shows the mandrel **915** after having been removed from the reservoir **905**. A cylindrical coating **960** has been formed on the mandrel **915**. The coating consists of the first portion **920** formed by the first suspension **910** and the second portion **955** formed by the second suspension **940**. The mandrel **915** is then placed in an oven in order to allow the coating to cure so as to form the cover **110**. The first suspension **910** thus formed the first material of the cover, and the second suspension **940** formed the second material.

FIG. **10** shows a system, generally indicated by **1000**, for transferring the cover **110** from the mandrel **915** to the shaft **105** of the device **100**. The system **1000** is shown in plan view in FIG. **10***a* and in cross-section in FIG. **10***b*. The system **1000** has a housing **1005**. A cylindrical tube **1010** passes through the housing **1005** and has a diameter configured to alternately receive the coated mandrel **915** and the shaft **105** of the device **100**, as described below.

FIG. **10***b* shows the interior **1015** of the system **1000**. A cylindrical space **1020** surrounds the cylinder **1010**. The wall **1022** that is common to the space **1020** and the cylinder **1010** contains a plurality of pores **1025** allowing the flow of air between the interior **1015** of the cylinder **1010** and the space **1020**. When the ends of the cylinder **1010** are sealed, as described below, the chambers **1015** and **1020** may be evacuated by removing air in the chambers through a tube **1027** that is connected to a source of negative pressure (not shown).

FIG. **10***c* shows the system **1000** after the mandrel **915** has been inserted into the cylindrical tube **1010**. As described above, the mandrel **915** is contained in the cover **110** that is to be transferred from the mandrel **915** to the shaft **105** of the device **100**.

As shown in FIG. **10***d*, the ends **128** of the cover **110** are then rolled off the mandrel **915** and onto the ends of the tube **1010**, thus sealing the ends of the cylinder **1010**. The chamber **1020** is then evacuated causing the cover **110** to dissociate from the mandrel **915** and associate with the inner surface of the cylinder **1010**, as shown in FIG. **10***e*. Dissociation of the cover **110** from the mandrel **915** may be enhanced if the mandrel is formed with a hollow core **1030** that is confluent with the exterior by pores **1035** in the wall of the mandrel **915**, as shown in FIG. **10***f*. A source of positive pressure (not shown) is applied to the core **1030** by means of a tube **1040**. The mandrel is then removed from the cylinder **1010** leaving the cover **110** mounted on the inner surface of the cylinder **1010**, as shown in FIG. **10***f*.

Now the shaft **105** of the device **100** is inserted into the cylinder **1010** as shown in FIG. **10***g*. The source of negative pressure is then disconnected from the tube **1027**, causing the cover **110** to dissociate from the wall of the cylinder **1010** and associate with the shaft **105** of the device **100**, as shown in FIG. **10***h*. The ends of the cover **110** are then unrolled from the cylinder **1010** onto the shaft **105**, and the shaft **105** is removed from the interior of the cylinder **1010** with the cover **110** in place.

Second Embodiment

FIG. **2***a* shows an indwelling device **200** in accordance with another embodiment of the invention. The device **200** has a proximal end **202**, a distal end **204**, and a cylindrical shaft **205** that may be solid or hollow. The shaft **205** is contained in an outer cover **210** having the general shape of a thin cylindrical shell. The outer cover **210** is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft **205**, and allowed to contract on the shaft **205**. The outer cover **210** is reversibly attached to the shaft **205** by circumferential elastic forces in the outer cover **210** that are exerted on the shaft **205**. This prevents slipping of the outer cover **210** over the shaft **205** during insertion of the device **200** into the body, and maintains the outer cover **210** on the shaft **205** after insertion.

As shown in the insert FIG. **2***a*-I of FIG. **2***a*, the shaft has a longitudinal groove **215** that forms a track for a blade **220**. The blade **220** is slidable along the groove **215**. During insertion into the body, the blade **220** is positioned at the distal end of the groove **215**. Between the shaft **205** and the outer cover **210** is a cord **230**. The cord is attached at one of its ends to the blade **220**. At its other end, the cord **215** extends beyond the proximal end of the coating.

FIG. **2***b* shows the device **200** after insertion into the body. The device **200** was inserted into the body through a hole **235** on the body surface **240**. The hole **235** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the cord **230** extends through the hole **235** and is exposed on the body surface. This is by way of example only, and the device may

in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord **230**. Relative movement of the shaft **205** and the outer cover **210** is prevented during insertion due to the circumferential elastic forces of the outer cover **210** on the shaft **205**.

At any time after insertion, the outer cover **210** may be detached from the device **200** by pulling the proximal end of the cord **230**. Pulling the cord **230** away from the body draws the blade **220** towards the proximal end of the shaft **205** thus making a longitudinal cut **233** in the cover **210**. (FIG. **2***c*). A guard **222** (FIG. **2***a*-I) on the blade prevents the blade from cutting any underlying covers. As the cord **230** continues to be pulled, cutting of the cover **210** progresses from the distal end towards the proximal end, until the cut extends along the entire length of the cover **210**. This detaches the outer cover **210** from the shaft **205**. The proximal end of the cut outer cover **210** may now be grasped and manually removed from the body leaving the device **200** in place. If after removal of the outer cover **210**, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Third Embodiment

FIG. **3***a* shows a device **300** in accordance with another embodiment of the invention. The device **300** has a proximal end **302**, a distal end **304**, and a cylindrical shaft **305**. The shaft **305** is contained in an outer cover **310** having the general shape of a thin cylindrical shell. The outer cover **310** is formed from a biocompatible, elastic material, such as latex. The outer cover **310** was formed from an inner cylindrical shell **322** and an outer cylindrical shell **324**. The inner and outer shells **322** and **324** are welded together at a first circular seam **326** at its distal end and a second circular seam **327** at its proximal end. The outer cover **310** was stretched over the shaft **305**, and allowed to constrict on the shaft **305**. The outer cover **310** is reversibly attached to the shaft **305** by circumferential elastic forces in the outer cover **310** that are exerted on the shaft **305**. This prevents movement of the outer cover **310** relative to the shaft **305** during insertion of the device **300** and maintains the outer cover **310** on the shaft **305** after insertion.

FIG. **3***b* shows the device of FIG. **3***a* after insertion into the body. The catheter **300** was inserted into the body through a hole **335** on the body surface **340**. The hole **335** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). The proximal end of the outer cover **310** extends through the hole **335** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the outer cover **310**. Relative movement of the shaft **305** and the outer cover **310** is prevented during insertion due to the circumferential elastic forces of the outer cover **310** on the shaft **305**.

At any time after insertion, the outer cover **310** may be detached from the device **300** by causing the outer cylindrical shell **324** to slide proximally over the inner cylindrical shell **322**. As shown in FIG. **3***c*, this may be accomplished by placing a thumb **330** and an index finger **332** on the outer cylindrical shell **324** and urging the outer cylindrical shell **324** to slide proximally over the inner cylindrical shell **322**, as indicated by the arrow **342** This draws the distal end of the inner cylindrical shell **322** into the outer shell **324**, while the remainder of the inner shell remains stationary, relative to the shaft **305**. As the outer shell **324** continues to slide proximally, the shaft **305** becomes progressively more exposed at its distal end, as shown in FIG. **3***d*. This process continues until the shaft **305** has been completely exposed and the outer cover **310** has been removed from the body. If after removal of the outer cover **310**, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Fourth Embodiment

FIG. **4***a* shows an indwelling device **400** in accordance with another embodiment of the invention. The device **400** has a proximal end **402**, a distal end **404**, and a cylindrical shaft **405** that may be solid or hollow. The shaft **405** is contained in an outer cover **410** having the general shape of a thin cylindrical shell. The outer cover **410** is formed from a strip of biocompatible material, such as latex or silicone rubber. The outer cover **410** is formed by winding the strip of biocompatible material in a helical pattern around the length of the shaft **405**. Consecutive turns of the helix overlap so as to completely cover the shaft **405**. The distal end **411** of the strip is tucked under the first few turns of the helix, so as to immobilize the distal end of the strip as shown in the insert to FIG. **4***a*. The proximal end of the strip is held in place by a ring **425**. The ring **425** has a lumen dimensioned to fit snugly on the shaft **405** and the proximal end of the outer cover **410**. This prevents slipping of the outer cover **410** over the shaft **405** during insertion of the device **400** into the body, and maintains the outer cover **410** on the shaft **405** after insertion.

FIG. **4***b* shows the device of FIG. **4***a* after insertion into the body. The device **400** was inserted into the body through a hole **435** on the body surface **440**. The hole **435** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device **400**, including the ring **425**, extends through the hole **435** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the device **400** and the ring **425**. Relative movement of the shaft **405** and the outer cover **410** is prevented during insertion due to the radial force of the ring **425** on the proximal end of the outer cover **410**, and the radial force of the last few turns of the helix on the distal end of the outer cover **410**.

At any time after insertion, the outer cover **410** may be detached from the device **400**. Referring to FIG. **4***c*, the ring **425** is removed from the shaft **405** and the outer cover **410** is unwound from its proximal end **408**. (FIG. **4***c*). The outer cover **410** continues to be unwound, until the distal end of the outer cover **410** is freed. The proximal end of the outer cover **410** may now be grasped and manually removed from the body leaving the device **400** in place. If after removal of the outer cover **410**, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Fifth Embodiment

FIG. **5***a* shows an indwelling device **500** in accordance with another embodiment of the invention. The device **500** has a proximal end **502**, a distal end **504**, and a cylindrical shaft **505** that may be solid or hollow. The shaft **505** is contained in an outer cover **510** having the general shape of a thin cylindrical shell. The outer cover **510** is formed from a biocompatible, rigid material, such as plastic or metal. One or more balloons **515** are located in a space **520** formed between

the outer cover **510** and the shaft **505**. In FIG. **5***a*, the balloons are shown in their deflated state. As shown in FIG. **5***b*, before inserting the device **500** into the body, the balloons **515** are inflated with a fluid such as air or water. A syringe **525** containing the fluid **530** is inserted into a valve **570**.

The balloons are inflated by opening the valve **570** and depressing the plunger **550** of the syringe. The fluid **530** is conducted from the syringe **525** through a first tube **560** and then through a second tube **565** running along the shaft **505** and then into each of the balloons **515**. When inflated, the balloons apply a pressure to both the shaft **515** and the outer cover **510**. The valve **540** is then closed to prevent fluid from leaving the balloons. The outer cover **510** thus becomes reversibly attached to the shaft **505** by the balloons **515** that are lodged between the outer cover **510** and the shaft **505**.

FIG. **5***c* shows the device of FIG. **5** and b after insertion into the body. The device **500** was inserted into the body through a hole **535** on the body surface **540**. The hole **535** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device extends through the hole **535** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cover **510**.

At any time after insertion, the outer cover **510** may be detached from the device **100** by deflating the balloons **515**. This may be done, for example, by inserting the syringe **530** into the valve **570** and drawing the fluid from the balloons so as to puncture the balloon by pulling on the plunger **550**. Once the balloons have been deflated, the proximal end of the device **500** may be grasped and manually removed from the body leaving the device **500** in place. If after removal of the outer cover **510**, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Sixth Embodiment

FIG. **7** shows an indwelling device **700** in accordance with another embodiment of the invention. The device **700** has a proximal end **702**, a distal end **704**, and a hollow cylindrical shaft **705**. The shaft **705** has a lumen **708**. In this embodiment, the cover **710** lines the inner surface of the hollow shaft **705**. The lumen **708** contains a cover **710** having the general shape of a thin cylindrical shell covering the wall of the lumen **708**. The cover **710** is formed from a biocompatible, rigid material, such as plastic. The proximal end of the cover **710** is glued to the lumen of a restraining ring **711**. A circumferential clamp **750** around the ring **711** secures the ring **711** to the proximal end **702** of the device **700**.

FIG. **7***b* shows the catheter of FIG. **7***a* after insertion into the body. The catheter **700** was inserted into the body through a hole **735** on the body surface **740**. The hole **735** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device extends through the hole **735** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the device **700**.

FIG. **7***b* further shows removal of the outer cover. The ring **711** is detached from the proximal end **702** of the device **700**, and the ring **711** is removed from the device **700** together with the cover **710** attached to it. As the ring **711** continues to be pulled away from the proximal end **702** of the device **700**, the cover **710** becomes attenuated and detaches from the inner surface of the shaft lumen **708**. If after removal of the outer cover **710**, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Seventh Embodiment

FIG. **8***a* shows an indwelling device **800** in accordance with a further embodiment of the invention. The device **800** has a proximal end **802**, a distal end **804**, and a cylindrical shaft **805** that may be solid or hollow. The shaft **805** is contained in an outer cover **810** having the general shape of a thin cylindrical shell. The outer cover **810** is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft **805**, and allowed to contract on the shaft **805**. The outer cover **810** is reversibly attached to the shaft **805** by circumferential elastic forces in the outer cover **810** that are exerted on the shaft **805**. This prevents slipping of the outer cover **810** over the shaft **805** during insertion of the device **800** into the body, and maintains the outer cover **810** on the shaft **805** after insertion.

The outer cover **810** has a line of perforations **820** extending along the length of the outer cover **810**. A ring **811** located on the shaft **805** contains a cord **830** that fixes the proximal end of the cover **810** onto the shaft **805**. As shown in FIG. **6**, the device **800** may optionally comprise a distally located annular clamp **615** that secures the distal end of the outer cover **810** to the shaft **805** and prevents debris from accumulating under the distal end of the outer cover **810** during insertion.

FIG. **8***b* shows the device **800** after insertion into the body. The device **800** was inserted into the body through a hole **835** on the body surface **840**. The hole **835** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device **800** extends through the hole **835** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord **830**. Relative movement of the shaft **805** and the outer cover **810** is prevented during insertion due to the circumferential elastic forces of the outer cover **810** on the shaft **805**.

At any time after insertion, the outer cover **810** may be detached from the device **800**. The cord **830** is released as shown in FIG. **8***c*. The proximal end of the perforation **820** is then torn. The cover **810** is then made to slide proximally over the shaft **805** as shown in FIG. **8***d*. This causes a new region of the perforation **820** to be exposed outside the body. This section of the perforation is then torn, and the cover **810** is then made to slide proximally over the shaft **805** (FIG. **8***d*). This process continues until all of the perforation **820** is completely torn and the cover is removed from the body. If after the removal of the outer cover **810**, a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Eighth Embodiment

FIG. **11***a* depicts a further embodiment of the device of the present invention, comprising an elongate catheter **1100** bearing an outer cover **1110** on its external surface. The cover **1110** is situated in close apposition to the outer surface of catheter **1100** along almost the entire length thereof. In some

versions of this embodiment, the cover may extend over the entire length of the device. In addition, two sealing elements—a distal sealing tip **1120** and a proximal sealing element **1130**—ensure that cover **1110** and the outer surface of catheter **1100** are in very close contact at their distal and proximal ends respectively, thus preventing the passage of possibly contaminating fluids (e.g. blood, urine, tissue fluid) between said catheter and said outer cover. In the typical device according to this embodiment shown in FIG. **11***a*, the distal sealing tip **1120** is elongate in shape, while the proximal sealing element **1130** is depicted as an annular ring. FIG. **11***b* depicts an alternative version of elongated distal sealing tip **1120**. The function of the perforations **1140** present in the distal half of this version of the sealing element is to provide a fluid pathway for use in cases in which it is desired that substances such as pharmaceutical agents and the like will be released from the indwelling device into the blood stream, duct or tissues. In yet other alternative forms of the distal sealing tip **1120**, the internal side of the distal half of the sealing tip, in which are present one or more apertures or perforations, may be covered with a mesh, thereby providing mechanical support and strength without interfering with the desired fluid flow channel provided by said apertures. It is to be further noted that it is possible to use many other shapes and forms of sealing elements, all of which are included in the scope of the present invention.

According to one preferred embodiment of the invention, a thin layer of mineral oil or similar biocompatible fluid is present between each adjacent pair of covers (in the case that the device is fitted with a sequential stack of covers, as described hereinabove) and/or between the innermost cover and the indwelling medical device itself. The presence of the inter-layer oil is advantageous both in providing an extra mechanism for preventing the ingress of contaminating fluids, as well as acting as a lubricant in order to facilitate the removal of the layer(s) from each other and/or from the surface of the medical device. In the case that mineral oil is incorporated into the device as described herein, the sealing elements may usefully be constructed of an oil-absorbing material.

In one particularly preferred embodiment of this type of device, both the outer cover **1110** and the distal sealing tip **1120** are made of medical grade polyurethane. In such a case, however, the polyurethane used to construct the cover **1110** will usually be of a harder grade (i.e. have a higher Shore rating) than that used to manufacture the sealing tip **1120**. However, other biocompatible materials such as silicones, PVC, mylar and nylon may also be used to manufacture the outer cover **1110** and distal sealing tip **1120**.

The proximal sealing element **1130** is most conveniently manufactured from polyurethane, but any other suitable material such as silicones, PVC, mylar and nylon may also be employed, and as such fall within the scope of the present invention as claimed.

The abovementioned materials that may be used to construct the medical device (e.g. catheter), outer cover and proximal and distal sealing elements may be used in any of the available degrees of hardness and color (including colorless transparent). In addition, any of these materials may be prepared such that they incorporate radio-opaque substances, for use as markers, as is known in the art. The embodiment of the device shown in FIG. **11***a* also incorporates a stationary cutting blade **1150** in its proximal, preferably extra-corporeal, portion. As shown in FIG. **11***a*, the proximal sealing element **1130** may be situated external to (and separate from) the blade. Alternatively, said element may be mounted close to the blade, within the blade housing itself (not shown).

Blade **1150** is used to assist in the removal of the outer cover **1110** (together with its attached biofilm deposits) in the following manner. Firstly, in the event that proximal sealing element **1130** is situated external to blade **1150** (as indicated in FIG. **11***a*), said element is opened and removed from the device and (if necessary) from the body. In the event that the proximal sealing element exists as an integral part of the blade housing, this stage is not required. In a further version of this embodiment of the invention, the proximal sealing element is constructed such that it may adopt two different conformations. In the first of these conformations, the sealing element is capable of preventing ingress of fluids into the space between the proximal end of the covers(s) and the medical device. In the second of these conformations, the proximal sealing element adopts a position such that the tight seal between the cover and underlying medical device is lost in the region of said element, thereby facilitating the removal of the cover layer and any biofilm attached thereto. Consequently, when the device is constructed in this manner, the first stage of the cover removal process consists of changing the conformation of the proximal sealing element from the first conformation to the second conformation.

The proximal margins of the outer cover **1110** are then grasped between the operator's fingers and drawn in a proximal direction toward the blade **1150**. Upon making contact with the blade, outer cover **1110** is incised at its free edge. This initial incision becomes elongated as the proximal margins of cover **1110** are drawn still further in a proximal direction, until the entire length of said cover has been cut longitudinally, and removed from contact with the catheter **1100** and finally entirely withdrawn from the body.

FIG. **11***c* illustrates the shape and form of cutting blade assembly **1150** in greater detail. The distal, ramp-like portion **1160** of the blade possesses a rounded, non-sharp profile which leads into the cutting edge **1170** of the blade assembly. It will thus be appreciated that when, as described hereinabove, the outer cover **1110** is drawn in a proximal direction towards cutting blade assembly **1150**, the distal, ramp-like portion **1160** will serve to guide the free proximal margin of said cover towards cutting edge **1170**. This guiding mechanism serves to prevent the kinking or buckling of cover **1110** that might otherwise occur if the proximal margin of said cover were to encounter a sharp, angled blade.

The cutting blade **1150** may be constructed from any suitable material that will permit said assembly to function as described hereinabove. In a preferred embodiment, however, the material used to construct the cutting blade **1150** is constructed from a sharpened metal such as medical grade stainless steel. In other embodiments, the blade may be constructed from other suitable biocompatible metals, as well as from rigid plastic materials.

The cutting blade assembly **1150** may be mounted in a stationary position at any convenient point at the proximal end of the device. In a particularly preferred embodiment, as shown in the exploded view given in FIG. **11***d*, cutting blade assembly **1150** is located within a multiple luer lock fitting **1180**, of any of the types that are well known in the art.

It is to be emphasized that the various components described in this embodiment of the device of the invention (i.e. the distal and proximal sealing elements and the stationary cutting blade) may all be incorporated into a single device, as illustrated in FIG. **11***a*. Alternatively, a single device may incorporate only one or two of the three elements disclosed hereinabove. It should further be noted that the presently-described embodiment is suitable for use both in conjunction

with a single cover and with a stack of covers, as is the case with the other embodiments disclosed and described hereinabove.

While specific embodiments of the invention have been described for the purpose of illustration, it will be understood that the invention may be carried out in practice by skilled persons with many modifications, variations and adaptations, without departing from its spirit or exceeding the scope of the claims.

The invention claimed is:

1. A medical device for insertion into a body, the device having at least one surface covered by and attached to at least one detachable cover, the cover being detachable from the surface and removed from the body any time after the device has been inserted in the body,

wherein the cover and the device are inserted in the body as a united device, such as the cover encapsulate and seals the medical device,

wherein the cover can be detached and pulled off of the device which remains in the body,

wherein the device cannot be pulled out from the cover while the cover remains within the body,

wherein the presence of said cover does not prevent the device from fulfilling its intended function, and wherein said medical device is selected from the group consisting of: (a) a catheter; (b) a cannula; (c) a drain; (d) a stent; (e) a pacemaker; and (f) an electrode.

2. The device according to claim **1**, wherein said device is a urinary catheter.

3. The device according to claim **1**, wherein said device is a venous catheter.

4. The device according to claim **1**, wherein said device is a dialysis catheter.

5. The device according to claim **1**, having a stack of at least two sequentially detachable covers, each cover being detachable either from the surface of the device or from the adjacent cover, and removed from the body while the device is within the body.

6. The device according to claim **5**, wherein the at least two covers are identical.

7. The device according to claim **1**, wherein the cover is formed from a material selected from the group consisting of: (a) rubber; (b) silicone rubber; (c) polyvinylchloride; (d) latex; (e) woven metal mesh; parylene; (g) polyurethane; (h) mylar; and (i) nylon.

8. The device according to claim **1**, wherein the cover is formed from a biocompatible material.

9. The device according to claim **1**, wherein the cover is formed from a non-allergenic material.

10. The device according to claim **1**, wherein the cover has a smooth surface.

11. The device according to claim **1**, wherein the cover has a rough surface.

12. The device according to claim **5**, containing a pharmaceutical agent between two adjacent covers.

13. The device according to claim **12**, wherein the pharmaceutical agent is an anti-infective agent.

14. The device according to claim **13**, wherein the anti-infective agent is an antibiotic drug.

15. The device according to claim **1**, wherein the cover is reversibly attached to a surface by elastic forces in the cover.

16. The device according to claim **1**, wherein the cover is detachable from the surface by tearing the cover.

17. The device according to claim **1**, wherein the cover is tearable along one or more preformed seams or perforations in the cover.

18. The device according to claim **1**, comprising a blade slidable over the surface so as to cut the cover and detach the cover from the surface.

19. The device according to claim **1**, further comprising a ring placed at a proximal part of the shaft to prevent materials from entering between the cover and the surface.

20. The device according to claim **1**, wherein the cover comprises an inner cylindrical shell and an outer cylindrical shell, the inner and outer cylindrical shells each having a distal end and a proximal end, the inner and outer cylindrical shells being attached to each other at their proximal ends and at their distal ends.

21. The device according to claim **1**, comprising one or more balloons located between the cover and the surface, the cover being attached to the surface by the inflated balloon, and detached from the surface when the balloons are not inflated, wherein before inserting the device into the body the balloon are in inflated, whereas once the balloon are deflated the cover can be grasped and removed from the body and wherein the inflated balloon seals the distal part of the cover.

22. The device according to claim **1**, wherein the cover is impenetrable to microorganisms.

23. The device according to claim **1**, wherein the cover is impenetrable to water.

24. The device according to claim **1** wherein the cover stores and releases a substance.

25. The device according to claim **24**, wherein the substance is an anti-microbial or anti-fungal compound.

26. The device according to claim **1**, wherein the cover has two parallel rows of perforations or seams separating a strip of the cover, the strip being attached at a distal end to a first end of a cord and a second end of the cord being accessible at a proximal end of the device.

27. The device according to claim **1**, further comprising a cutter slidable along the surface of the device, the cutter being configured to cut the cover when sliding along the surface.

28. The device according to claim **1**, wherein the cover has a row of perforations such that when the proximal end of the perforation is torn, the cover may be made to slide over the surface in a proximal direction.

29. The device according to claim **1**, further comprising a distal sealing tip, wherein said tip is capable of preventing ingress of fluids into the space between the distal end of the cover(s) and the medical device, wherein the seal is pulled of with the detachable cover.

30. The device according to claim **29**, wherein the distal sealing tip is made of polyurethane.

31. The device according to claim **1**, further comprising a proximal sealing element, wherein said element is capable of preventing ingress of fluids into the space between the proximal end of the covers(s) and the medical device.

32. The device according to claim **1**, further comprising a proximal sealing element, wherein said element is constructed such that it may adopt two distinct conformations, such that when the sealing element is in the first conformation, said element is capable of preventing ingress of fluids into the space between the proximal end of the covers(s) and the medical device, and when the sealing element is in the second position, said element permits easy removal of the outer cover, together with the associated biofilm.

33. The device according to claim **31**, wherein the proximal sealing element is made of polyurethane.

34. The device according to claim **1**, further comprising a fixed blade attached to the proximal end of said device, such that said blade is capable of incising the cover, when said cover is pulled proximally toward said blade, wherein the blade is located within an encapsulated lock which envelopes

the cover at its proximal end, and wherein the blade is oriented at an angle to the cover surface, at distance from the proximal end of the cover.

35. A method for preventing biofilm buildup on the surface of an indwelling medical device that has been inserted into the body of a subject using the device of claim **1**, said method comprising the steps of; a) inserting said device together with its attached cover into the body of the subject; b) detaching the cover from the outer surface of the medical device and removing said cover from the body together with any biofilm deposited on the surface of said cover, while leaving the device inside the body such that it may continue to fulfill its intended function.

36. A method for preventing biofilm buildup on the surface of an indwelling medical device that has been inserted into the body of a subject, using the device of claim **1**, said method comprising the steps of: a) inserting said device together with its attached cover into the body of the subject; b) detaching the outermost cover from the stack of sequentially detachable covers and removing said cover from the body together with any biofilm deposited on the outer surface thereof, while leaving the device inside the body such that it may continue to fulfill its intended function; c) subsequently repeating step (c) for the one or more remaining outermost covers.

37. The method according to claim **35**, wherein the device is a urinary catheter.

38. The method according to claim **35**, wherein the device is a venous catheter.

39. The method according to claim **35**, wherein the device is a dialysis catheter.

40. The device of claim **29**, wherein the seal is integral part of the cover or attached to the cover.

41. The device of claim **1**, wherein the detachable cover cannot be inserted back into the body or is attached to the device once it was pulled of.

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